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National Health (Listing of Pharmaceutical Benefits) Instrument 2024

made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the
National Health Act 1953

This Instrument is in 8 volumes

- Volume 1: sections 1–24 and Schedule 1 (Part 1: A–C)
- Volume 2: Schedule 1 (Part 1: D–K)
- Volume 3: Schedule 1 (Part 1: L–P)
- Volume 4: Schedule 1 (Part 1: Q–Z, Part 2), Schedules 2 and 3
- Volume 5: Schedule 4 (Part 1: C4000–C9999)
- Volume 6: Schedule 4 (Part 1: C10000–C12999)
- Volume 7: Schedule 4 (Part 1: C13000 onwards, Part 2)**
- Volume 8: Schedule 5, Schedule 6 and Endnotes

Each volume has its own contents

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Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

Clause 1

Schedule 4—Circumstances, purposes, conditions and variations

Note: See sections 13, 15, 16, 19 and 23.

Part 1—Circumstances, purposes and conditions

1 Circumstances, purposes and conditions

The following table sets out:

- (a) circumstances for circumstances codes, for the purposes of section 13 and 23; and
- (b) purposes for purposes codes, for the purposes of sections 15 and 16; and
- (c) for the purposes of section 19, information relating to how authorisation is obtained when the circumstances or conditions for writing a prescription include an authorisation requirement.

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13001	P13001	CN13001	Midostaurin	Acute Myeloid Leukaemia Induction / Consolidation therapy Patient must not have received prior chemotherapy as induction therapy for this condition; or The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy and the patient must not have progressive disease; AND The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority; AND The condition must not be acute promyelocytic leukaemia; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.</p> <p>A maximum of 6 cycles will be authorised under this restriction in a lifetime.</p> <p>Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.</p> <p>The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.</p> <p>If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.</p> <p>Progressive disease is defined as the presence of any of the following:</p> <ul style="list-style-type: none"> Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia. <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p>	
C13004	P13004	CN13004	Trastuzumab emtansine	<p>Early HER2 positive breast cancer</p> <p>Initial adjuvant treatment</p> <p>The treatment must be prescribed within 12 weeks after surgery; AND</p> <p>Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report; AND</p> <p>Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery; AND</p>	<p>Compliance with Written Authority Required procedures</p>

Schedule 4 Circumstances, purposes, conditions and variations

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND</p> <p>The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined.</p> <p>Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery.</p> <p>The pathology report must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13006	P13006	CN13006	Ponatinib	<p>Chronic Myeloid Leukaemia (CML)</p> <p>Subsequent continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have maintained a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells at 12 month intervals. or</p> <p>Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% on the international scale at 12 month intervals.</p> <p>A pathology report demonstrating the patient's cytogenetic response or a peripheral blood level of BCR-ABL must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures
C13007	P13007	CN13007	Lapatinib	<p>Metastatic (Stage IV) HER2 positive breast cancer</p> <p>Initial treatment</p> <p>Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; AND</p> <p>The treatment must be in combination with capecitabine; AND</p> <p>Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; or</p> <p>Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; or</p> <p>Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; or</p> <p>Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; AND</p> <p>The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition; AND</p> <p>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.</p> <p>Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(i) details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and</p> <p>(ii) date of last treatment with a taxane and total number of cycles; or</p> <p>(iii) dates of treatment with trastuzumab and pertuzumab; or</p> <p>(iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or</p> <p>(v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab</p>	

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Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.</p> <p>All reports must be documented in the patient's medical records.</p> <p>Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.</p> <p>If the application is submitted through HPOS upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13008	P13008	CN13008	Zanubrutinib	<p>Waldenstrom macroglobulinaemia</p> <p>Initial treatment</p> <p>The condition must have relapsed or be refractory to at least one prior chemo-immunotherapy; or</p> <p>Patient must be unsuitable for treatment with chemo-immunotherapy, defined by a Cumulative Illness Rating Scale of 6 or greater, if untreated (i.e. treatment-naive) for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND</p> <p>Patient must be untreated with a Bruton's tyrosine kinase inhibitor for this condition.</p> <p>or</p> <p>Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this condition.</p>	Compliance with Authority Required procedures
C13010	P13010	CN13010	Azacitidine	<p>Acute Myeloid Leukaemia</p> <p>Initial treatment</p> <p>The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination; AND</p> <p>The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.</p> <p>The following reports must be documented in the patient's medical records</p>	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and (b) full blood examination report.	
C13011	P13011	CN13011	Azacitidine	Myelodysplastic syndrome Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
C13012	P13012	CN13012	Azacitidine	Acute Myeloid Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease.	Compliance with Authority Required procedures - Streamlined Authority Code 13012
C13013	P13013	CN13013	Midostaurin	Acute Myeloid Leukaemia Maintenance therapy - Initial treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin confirmed through a bone marrow biopsy pathology report; AND Patient must not be undergoing or have undergone a stem cell transplant; AND The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority. A maximum of 3 cycles will be authorised under this restriction in a lifetime. Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.</p> <p>Progressive disease is defined as the presence of any of the following: Leukaemic cells in the CSF; Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; Extramedullary leukaemia.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and</p> <p>(b) confirmation that the patient does not have progressive disease; and</p> <p>(c) details (date, unique identifying number/code or provider number) of a recent bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient is in complete remission; and</p> <p>(d) details (date, unique identifying number/code or provider number) of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13015	P13015	CN13015	Azacitidine	<p>Chronic Myelomonocytic Leukaemia</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not have progressive disease. Up to 6 cycles will be authorised.	
C13017	P13017	CN13017	Trastuzumab emtansine	Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The treatment must not exceed a lifetime total of one continuous course for this PBS indication.	Compliance with Authority Required procedures
C13018	P13018	CN13018	Pertuzumab	Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; AND Patient must have a WHO performance status of 0 or 1; AND Patient must not have received prior anti-HER2 therapy for this condition; AND Patient must not have received prior chemotherapy for this condition; AND The treatment must be in combination with trastuzumab and a taxane; AND The treatment must not be in combination with nab-paclitaxel; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. Details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) must be provided at the time of application.	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The pathology report must be documented in the patient's medical records. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.	
C13022	P13022	CN13022	Ponatinib	Chronic Myeloid Leukaemia (CML) First continuing treatment Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals. or Patient must demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals. The first continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or (ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
C13025	P13025	CN13025	Ponatinib	Chronic Myeloid Leukaemia (CML) Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; or Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal; AND Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority. or Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal. or Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis. Failure of an adequate trial of dasatinib or nilotinib is defined as 1. Lack of response to dasatinib or nilotinib therapy, defined as either (i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR 4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or</p> <p>2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or</p> <p>3. Peripheral basophils greater than or equal to 20%; or</p> <p>4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or</p> <p>5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).</p> <p>Blast crisis is defined as either</p> <p>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or</p> <p>2. Extramedullary involvement other than spleen and liver.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or</p> <p>(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and</p> <p>(iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.</p> <p>All reports must be documented in the patient's medical records</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	
C13029	P13029	CN13029	Azacitidine	<p>Chronic Myelomonocytic Leukaemia Initial treatment</p> <p>The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report; AND</p> <p>The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.</p> <p>The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and</p> <p>(b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following reports must be documented in the patient's medical records</p> <p>(a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and</p> <p>(b) full blood examination report</p> <p>No more than 3 cycles will be authorised under this restriction in a patient's lifetime.</p>	Compliance with Written Authority Required procedures
C13030	P13030	CN13030	Ponatinib	<p>Chronic Myeloid Leukaemia (CML) Initial treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report; AND</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority. or</p> <p>Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority. or</p> <p>Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority.</p> <p>Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as</p> <ol style="list-style-type: none">1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either <ol style="list-style-type: none">(i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR <ol style="list-style-type: none">2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. <p>Accelerated phase is defined by the presence of 1 or more of the following</p> <ol style="list-style-type: none">1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or</p> <p>3. Peripheral basophils greater than or equal to 20%; or</p> <p>4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or</p> <p>5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).</p> <p>Blast crisis is defined as either</p> <p>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or</p> <p>2. Extramedullary involvement other than spleen and liver.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or</p> <p>(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and</p> <p>(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and</p> <p>(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	

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				Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	
C13034	P13034	CN13034	Diroximel fumarate	<p>Multiple sclerosis</p> <p>Continuing treatment</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not show continuing progression of disability while on treatment with this drug.</p> <p>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13034
C13035	P13035	CN13035	Abemaciclib	<p>Locally advanced or metastatic breast cancer</p> <p>Initial treatment</p> <p>Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; or</p> <p>Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND</p> <p>The condition must be hormone receptor positive; AND</p> <p>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND</p> <p>The condition must be inoperable; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; or</p> <p>The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND</p> <p>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy;</p> <p>Patient must not be premenopausal.</p>	
C13036	P13036	CN13036	Abemaciclib	<p>Locally advanced or metastatic breast cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND</p> <p>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy;</p> <p>Patient must not be premenopausal.</p>	Compliance with Authority Required procedures
C13037	P13037	CN13037	Ribociclib	<p>Locally advanced or metastatic breast cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND</p> <p>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND</p> <p>Patient must require dosage reduction requiring a pack of 42 tablets;</p> <p>Patient must not be premenopausal.</p>	Compliance with Authority Required procedures

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C13039	P13039	CN13039	Infliximab	<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made</p> <p>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND</p> <p>Patient must be undergoing treatment with this benefit where:</p> <p>(i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The PBS administrator will confirm that</p> <p>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;</p> <p>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.</p>	Compliance with Authority Required procedures
C13040	P13040	CN13040	Infliximab	<p>Severe psoriatic arthritis</p> <p>Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true:</p> <p>(i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13043	P13043	CN13043	Infliximab	<p>of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; or</p> <p>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true:</p> <p>(i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions;</p> <p>Patient must be at least 18 years of age.</p> <p>Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.</p> <p>Severe psoriatic arthritis</p> <p>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>The treatment must have both:</p> <p>(i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response to treatment is defined as</p>	Compliance with Authority Required procedures

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				<p>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.</p>	
C13045	P13045	CN13045	Infliximab	<p>Moderate to severe ulcerative colitis Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The PBS administrator will confirm that</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient; (ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.	
C13049	P13049	CN13049	Paliperidone	Schizophrenia Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months. or Patient must have previously received and be stabilised on PBS-subsidised paliperidone six-monthly injection for at least one cycle.	Compliance with Authority Required procedures - Streamlined Authority Code 13049
C13055	P13055	CN13055	Palbociclib	Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; or Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with a non-steroidal aromatase inhibitor; or The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; Patient must not be premenopausal.	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13056	P13056	CN13056	Infliximab	<p>Complex refractory Fistulising Crohn disease</p> <p>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response is defined as</p> <p>(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or</p> <p>(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.</p> <p>The most recent fistula assessment must be no more than 1 month old at the time of application.</p>	Compliance with Authority Required procedures
C13058	P13058	CN13058	Infliximab	<p>Severe chronic plaque psoriasis</p> <p>Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true:</p> <p>(i) the most recent authority application did not specify the full quantity of repeat</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13061	P13061	CN13061	Infliximab	<p>prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; or</p> <p>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true:</p> <p>(i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions;</p> <p>Patient must be at least 18 years of age.</p> <p>Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.</p> <p>Moderate to severe ulcerative colitis</p> <p>Balance of supply for Initial treatment, Continuing treatment - subcutaneous form</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; or</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form;</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Authority Required procedures

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C13066	P13066	CN13066	Palbociclib	<p>Locally advanced or metastatic breast cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND</p> <p>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy;</p> <p>Patient must not be premenopausal.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p>	Compliance with Authority Required procedures
C13068	P13068	CN13068	Infliximab	<p>Severe Crohn disease</p> <p>Balance of supply for Initial treatment, Continuing treatment - subcutaneous form</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; or</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form;</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13069	P13069	CN13069	Infliximab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made</p> <p>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND</p> <p>Patient must be undergoing treatment with this benefit where:</p> <p>(i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The PBS administrator will confirm that</p> <p>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;</p> <p>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.</p>	Compliance with Authority Required procedures
C13070	P13070	CN13070	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Grandfathered patient - Face, hand, foot or Whole body - Balance of Supply</p> <p>Must be treated by a dermatologist; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Whole body restriction to complete 24 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Face, hand, foot restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures

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C13072	P13072	CN13072	Diroximel fumarate	<p>Multiple sclerosis Initial treatment</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support). Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13072
C13074	P13074	CN13074	Ribociclib	<p>Locally advanced or metastatic breast cancer Initial treatment</p> <p>Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; or Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND</p> <p>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND</p> <p>Patient must require dosage reduction requiring a pack of 42 tablets;</p> <p>Patient must not be premenopausal.</p>	
C13077	P13077	CN13077	Infliximab	<p>Ankylosing spondylitis</p> <p>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made</p> <p>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND</p> <p>Patient must be undergoing treatment with this benefit where:</p> <p>(i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The PBS administrator will confirm that</p> <p>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;</p> <p>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.</p>	Compliance with Authority Required procedures
C13078	P13078	CN13078	Infliximab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made</p>	Compliance with Authority Required procedures

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				<p>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND</p> <p>Patient must be undergoing treatment with this benefit where:</p> <p>(i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The PBS administrator will confirm that</p> <p>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;</p> <p>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.</p>	
C13079	P13079	CN13079	Infliximab	<p>Severe chronic plaque psoriasis</p> <p>Continuing treatment (whole body, or, face/hand/foot) with subcutaneous form or switching from intravenous form to subcutaneous form</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>The treatment must have both:</p> <p>(i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Where the condition is affecting the whole body, an adequate response to treatment is defined as</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by at least 75%, or, is sustained at this level, when compared with the baseline value for this treatment cycle. State the qualifying PASI score in the authority application.</p> <p>Where the condition is affecting the face/hand/foot, an adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing</p> <p>(i) A reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or, sustained at this level, as compared to the baseline values. Indicate the rating (0=none, 1=slight) for each of these 3 observations in the authority application for each affected area; or</p> <p>(ii) A reduction by at least 75% in the skin area affected, or, sustained at this level, as compared to the baseline value for this treatment cycle. State the qualifying numerical percentage figure in the authority application for each affected area.</p> <p>All assessment findings must be no more than 1 month old at the time of application. Response assessments must be performed on the same affected area assessed at baseline.</p>	
C13080	P13080	CN13080	Infliximab	<p>Severe Crohn disease</p> <p>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made</p> <p>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND</p> <p>Patient must be undergoing treatment with this benefit where:</p> <p>(i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p>	Compliance with Authority Required procedures

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				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The PBS administrator will confirm that</p> <p>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;</p> <p>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.</p>	
C13082	P13082	CN13082	Paliperidone	<p>Schizophrenia</p> <p>Patient must have previously received and be stabilised on PBS-subsidised paliperidone three-monthly injection for at least one cycle. or</p> <p>Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13082
C13084	P13084	CN13084	Ribociclib	<p>Locally advanced or metastatic breast cancer</p> <p>Initial treatment</p> <p>Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; or</p> <p>Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal;</p> <p>AND</p> <p>The condition must be hormone receptor positive; AND</p> <p>The condition must be human epidermal growth factor receptor 2 (HER2) negative;</p> <p>AND</p> <p>The condition must be inoperable; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND</p> <p>The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; or</p> <p>The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; Patient must not be premenopausal.	
C13093	P13093	CN13093	Ribociclib	Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; Patient must not be premenopausal.	Compliance with Authority Required procedures
C13094	P13094	CN13094	Infliximab	Complex refractory Fistulising Crohn disease Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; or Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit,	Compliance with Authority Required procedures

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C13096	P13096	CN13096	Infliximab	<p>(ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; Patient must be at least 18 years of age. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.</p> <p>Ankylosing spondylitis Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis; AND Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; or Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; Patient must be at least 18 years of age. Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'.</p>	Compliance with Authority Required procedures

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C13097	P13097	CN13097	Infliximab	<p>Severe psoriatic arthritis</p> <p>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made</p> <p>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND</p> <p>Patient must be undergoing treatment with this benefit where:</p> <p>(i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The PBS administrator will confirm that</p> <p>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;</p> <p>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application.</p>	Compliance with Authority Required procedures
C13099	P13099	CN13099	Ribociclib	<p>Locally advanced or metastatic breast cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>The treatment must be in combination with one of:</p> <p>(i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND</p> <p>Patient must require dosage reduction requiring a pack of 21 tablets; AND</p> <p>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy;</p>	Compliance with Authority Required procedures

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C13104	P13104	CN13104	Infliximab	<p>Patient must not be premenopausal.</p> <p>Severe active rheumatoid arthritis</p> <p>Balance of supply for Initial treatment, Continuing treatment - subcutaneous form</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND</p> <p>The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; or</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form;</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Authority Required procedures
C13105	P13105	CN13105	Ribociclib	<p>Locally advanced or metastatic breast cancer</p> <p>Initial treatment</p> <p>Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; or</p> <p>Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND</p> <p>The condition must be hormone receptor positive; AND</p> <p>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND</p> <p>The condition must be inoperable; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; or</p> <p>The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND</p> <p>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND</p> <p>Patient must require dosage reduction requiring a pack of 21 tablets;</p> <p>Patient must not be premenopausal.</p>	
C13122	P13122	CN13122	Ciclosporin	<p>Severe psoriasis Management (initiation, stabilisation and review of therapy)</p> <p>The condition must be ineffective to other systemic therapies; or</p> <p>The condition must be inappropriate for other systemic therapies; AND</p> <p>The condition must have caused significant interference with quality of life; AND</p> <p>Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13122
C13127	P13127	CN13127	Ruxolitinib	<p>High risk and intermediate-2 risk myelofibrosis Initial treatment</p> <p>The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and</p> <p>(b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p>	Compliance with Authority Required procedures

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				(i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C13128	P13128	CN13128	Ruxolitinib	High risk and intermediate-2 risk myelofibrosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
C13130	P13130	CN13130	Ruxolitinib	Intermediate-1 risk myelofibrosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
C13132	P13132	CN13132	Imatinib	Malignant gastrointestinal stromal tumour Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be given at a dose not exceeding 600 mg per day. Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved. A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347 472-80.)	Compliance with Authority Required procedures - Streamlined Authority Code 13132
C13134	P13134	CN13134	Brentuximab vedotin	CD30 positive peripheral T-cell lymphoma, non-cutaneous type Initial treatment Patient must have histological confirmation of CD30 expression in at least 3% of malignant cells; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be for first line therapy for this condition; AND The treatment must be for curative intent; AND The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND The treatment must not be more than 6 treatment cycles under this restriction in a lifetime. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample from an Approved Pathology Authority showing CD30 positivity of at least 3% malignant cells; and (b) The date of initial diagnosis of Peripheral T-cell lymphoma. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13152	P13152	CN13152	Sunitinib	<p>Metastatic or unresectable malignant gastrointestinal stromal tumour Initial treatment The condition must not be resectable; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must have previously failed or be intolerant to imatinib mesilate. Applications for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and</p>	Compliance with Written Authority Required procedures

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				(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.	
C13153	P13153	CN13153	Sunitinib	Metastatic or unresectable malignant gastrointestinal stromal tumour Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must not be resectable; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 13153
C13165	P13165	CN13165	Decitabine with cedazuridine	Chronic Myelomonocytic Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
C13166	P13166	CN13166	Gilteritinib	Relapsed or refractory Acute Myeloid Leukaemia Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must not be acute promyelocytic leukaemia; AND The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 prior to treatment initiation.	Compliance with Authority Required procedures

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				The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.	
C13168	P13168	CN13168	Ciclosporin	Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; or The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life; AND Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 13168
C13173	P13173	CN13173	Ruxolitinib	Intermediate-1 risk myelofibrosis Initial treatment The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report; AND Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and	Compliance with Authority Required procedures

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C13175	P13175	CN13175	Sonidegib Vismodegib	<p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Metastatic or locally advanced basal cell carcinoma (BCC) Initial treatment</p> <p>The condition must be inappropriate for surgery; AND The condition must be inappropriate for curative radiotherapy; AND Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; or Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal; AND Patient must not receive more than 16 weeks of treatment under this restriction. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and</p> <p>(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and</p> <p>(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.</p> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Inappropriate for surgery is defined as</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or</p> <p>(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or</p> <p>(iii) Medical contraindication to surgery.</p> <p>(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</p> <p>(ii) Limitations due to location of tumour; or</p> <p>(iii) Limitations due to cumulative prior radiotherapy dose; or</p> <p>(iv) Progressive disease despite prior irradiation of locally advanced BCC.</p> <p>Inappropriate for curative radiotherapy is defined as</p> <p>(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</p> <p>(ii) Limitations due to location of tumour; or</p> <p>(iii) Limitations due to cumulative prior radiotherapy dose; or</p> <p>(iv) Progressive disease despite prior irradiation of locally advanced BCC.</p> <p>For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.</p>	
C13177	P13177	CN13177	Vorinostat	<p>Cutaneous T-cell lymphoma</p> <p>Initial treatment</p> <p>Patient must have received systemic treatment with chemotherapy; AND</p> <p>Patient must demonstrate relapsed or chemotherapy-refractory disease; AND</p> <p>Patient must be ineligible for stem cell transplant; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p>	Compliance with Authority Required procedures

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C13179	P13179	CN13179	Brentuximab vedotin	<p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>CD30 positive cutaneous T-cell lymphoma</p> <p>Initial treatment</p> <p>Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma; AND</p> <p>Patient must have CD30 positivity of at least 3% of malignant cells; AND</p> <p>Patient must have a diagnosis of mycosis fungoides; or</p> <p>Patient must have a diagnosis of Sezary syndrome; or</p> <p>Patient must have a diagnosis of primary cutaneous anaplastic large cell lymphoma; AND</p> <p>Patient must have received prior systemic treatment for this condition; AND</p> <p>The condition must be relapsed or refractory; AND</p> <p>The treatment must not exceed 4 cycles under this restriction in a lifetime; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) details (date, unique identifying number/code or provider number) of the histopathology report from an Approved Pathology Authority demonstrating the patient has a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and</p> <p>(b) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample or of a flow cytometric analysis of lymphoma cells of the blood showing CD30 positivity of at least 3% of malignant cells; and</p> <p>(c) Date of commencement and completion of the most recent prior systemic treatment.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C13181	P13181	CN13181	Brentuximab vedotin	<p>CD30 positive cutaneous T-cell lymphoma</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved an objective response with this drug; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>The treatment must not exceed 12 cycles under this restriction in a lifetime.</p> <p>An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria.</p>	Compliance with Authority Required procedures
C13182	P13182	CN13182	Brentuximab vedotin	<p>CD30 positive systemic anaplastic large cell lymphoma</p> <p>Initial treatment</p> <p>The treatment must be for curative intent; AND</p> <p>Patient must have undergone appropriate prior front-line curative intent chemotherapy; AND</p> <p>Patient must demonstrate relapsed or chemotherapy-refractory disease; AND</p> <p>Patient must have responded to PBS-subsidised treatment with this drug if previously used for initial treatment of CD30 positive peripheral T-cell lymphoma, non-cutaneous type; AND</p> <p>The treatment must not exceed 4 cycles under this restriction.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) details (date, unique identifying number or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and</p> <p>(b) The date of initial diagnosis of systemic anaplastic large cell lymphoma; and</p>	Compliance with Authority Required procedures

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C13184	P13184	CN13184	Entrectinib	<p>(c) Dates of commencement and completion of front-line curative intent chemotherapy; and</p> <p>(d) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Initial treatment</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; or</p> <p>Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal; AND</p> <p>Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be documented in the patient's medical records</p> <p>(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.</p>	
C13186	P13186	CN13186	Crizotinib	<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Continuing treatment</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Authority Required procedures
C13205	P13205	CN13205	Decitabine with cedazuridine	<p>Chronic Myelomonocytic Leukaemia</p> <p>Initial treatment</p> <p>The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report; AND</p> <p>The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.</p> <p>No more than 3 cycles will be authorised under this restriction in a patient's lifetime.</p> <p>The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and</p> <p>(b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p>	Compliance with Authority Required procedures

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				(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following reports must be documented in the patient's medical records (a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and (b) full blood examination report	
C13207	P13207	CN13207	Cabazitaxel	Castration resistant metastatic carcinoma of the prostate The treatment must be in combination with prednisone or prednisolone; AND The condition must be resistant to treatment with docetaxel; or Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel; AND The treatment must not be used in combination with a novel hormonal drug; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.	Compliance with Authority Required procedures - Streamlined Authority Code 13207
C13208	P13208	CN13208	Brentuximab vedotin	Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.	Compliance with Authority Required procedures
C13209	P13209	CN13209	Brentuximab vedotin	Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND	Compliance with Authority Required procedures

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				<p>Patient must not be suitable for ASCT for this condition; or Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have experienced a relapsed CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; or Patient must have experienced a refractory CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; AND Patient must not receive more than 4 cycles of treatment under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS upload or mail, it must include (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13212	P13212	CN13212	Brentuximab vedotin	<p>CD30 positive peripheral T-cell lymphoma, non-cutaneous type Continuing treatment The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND Patient must have completed 6 initial cycles of PBS-subsidised treatment with this drug for this indication; AND Patient must have achieved at least a partial response to the 6 initial cycles of treatment with a combination of this drug and cyclophosphamide, doxorubicin and prednisone for this indication; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as (a) Positron emission tomography-based response lymph nodes and extralymphatic sites - a score of 4 (uptake moderately > liver), or 5 (uptake markedly higher than</p>	Compliance with Authority Required procedures

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C13222	P13222	CN13222	Nusinersen	<p>liver and/or new lesions), with reduced uptake compared with baseline and residual mass(es) of any size; nonmeasured lesions - not applicable; organ enlargement - not applicable; new lesions - none; bone marrow - residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan; OR</p> <p>(b) Computed tomography-based response lymph nodes and extralymphatic sites - greater than or equal to 50% decrease in the sum of the product of the perpendicular diameters for multiple lesions, of up to six (6) target measurable nodes and extranodal sites; non-measured lesions - absent/normal, regressed but no increase; new lesions - none; bone marrow - not applicable.</p> <p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Initial PBS-subsidised treatment in a child The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug; Patient must be of an age that is prior to their 19th birthday at the time of this authority application; Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC); Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); or</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13230	P13230	CN13230	Dapagliflozin Empagliflozin	<p>Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are (i) Failure to meet or regression in ability to perform age-appropriate motor milestones, (ii) Proximal weakness, (iii) Hypotonia, (iv) Absence of deep tendon reflexes, (v) Any active denervation or chronic neurogenic changes found on electromyography, (vi) A compound muscle action potential below normative values for an age-matched child. In this authority application, confirm (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy, (2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday, (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.</p>	Compliance with Authority Required procedures -

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				<p>(i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND</p> <p>Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m² inclusive prior to initiating treatment with this drug; AND</p> <p>Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug; AND</p> <p>Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND</p> <p>Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND</p> <p>Patient must be stabilised, for at least 4 weeks, on either:</p> <p>(i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug.</p> <p>Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.</p>	Streamlined Authority Code 13230
C13231	P13231	CN13231	Brentuximab vedotin	<p>Relapsed or Refractory Hodgkin lymphoma</p> <p>Continuing treatment</p> <p>Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND</p> <p>Patient must not be suitable for ASCT for this condition; or</p> <p>Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not receive more than 12 cycles of treatment under this restriction.</p> <p>The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13233	P13233	CN13233	Crizotinib	<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Initial treatment</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND</p> <p>Patient must have a WHO performance status of 2 or less;</p> <p>Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be documented in the patient's medical records</p> <p>(a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.</p>	Compliance with Authority Required procedures
C13236	P13236	CN13236	Vedolizumab	<p>Severe Crohn disease</p> <p>Balance of supply - subcutaneous form</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); or</p>	Compliance with Authority Required procedures

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				<p>Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form. or</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.</p>	
C13237	P13237	CN13237	Vedolizumab	<p>Moderate to severe ulcerative colitis</p> <p>Balance of supply - subcutaneous form</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); or</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form. or</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.</p>	Compliance with Authority Required procedures
C13241	P13241	CN13241	Decitabine with cedazuridine	<p>Acute Myeloid Leukaemia</p> <p>Initial treatment</p> <p>The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination; AND</p> <p>The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.</p> <p>The following reports must be documented in the patient's medical records</p> <p>(a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and</p> <p>(b) full blood examination report.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13242	P13242	CN13242	Gilteritinib	<p>Relapsed or refractory Acute Myeloid Leukaemia</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>Patient must not be undergoing or have undergone a stem cell transplant.</p> <p>Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.</p> <p>If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.</p> <p>Progressive disease is defined as the presence of any of the following</p> <p>(a) Leukaemic cells in the CSF; or</p> <p>(b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or</p> <p>(c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or</p> <p>(d) Extramedullary leukaemia.</p>	Compliance with Authority Required procedures
C13246	P13246	CN13246	Vorinostat	<p>Cutaneous T-cell lymphoma</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p>	Compliance with Authority Required procedures
C13250	P13250	CN13250	Crizotinib	<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Initial treatment</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p>	Compliance with Authority Required procedures

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C13251	P13251	CN13251	Crizotinib	<p>The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing; AND</p> <p>Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition. or</p> <p>Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be documented in the patient's medical records</p> <p>(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13257	P13257	CN13257	Decitabine with cedazuridine	Myelodysplastic syndrome Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease. Up to 6 cycles will be authorised.	Compliance with Authority Required procedures
C13258	P13258	CN13258	Decitabine with cedazuridine	Acute Myeloid Leukaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease.	Compliance with Authority Required procedures - Streamlined Authority Code 13258
C13259	P13259	CN13259	Brentuximab vedotin	Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must have undergone a primary autologous stem cell transplant (ASCT); AND Patient must have experienced a relapsed CD30+ Hodgkin lymphoma post ASCT; or Patient must have experienced a refractory CD30+ Hodgkin lymphoma post ASCT; AND Patient must not receive more than 4 cycles of treatment under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS upload or mail, it must include (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Authority Required procedures
C13260	P13260	CN13260	Sonidegib	Metastatic or locally advanced basal cell carcinoma (BCC) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Written Authority Required procedures

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				<p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must remain inappropriate for surgery; AND</p> <p>The condition must remain inappropriate for curative radiotherapy; AND</p> <p>Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) Confirmation from the treating doctor that the disease has not progressed; and</p> <p>(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.</p> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Inappropriate for surgery is defined as</p> <p>(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or</p> <p>(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or</p> <p>(iii) Medical contraindication to surgery.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. Inappropriate for curative radiotherapy is defined as (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.	
C13261	P13261	CN13261	Brentuximab vedotin	CD30 positive systemic anaplastic large cell lymphoma Continuing treatment Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime.	Compliance with Authority Required procedures
C13267	P13267	CN13267	Decitabine with cedazuridine	Myelodysplastic syndrome Initial treatment The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination; AND The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); or The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS); AND The condition must have up to 20% marrow blasts according to World Health Organisation (WHO) Classification.	Compliance with Authority Required procedures

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				<p>Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations</p> <p>(a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR</p> <p>(b) 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR</p> <p>(c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR</p> <p>(d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR</p> <p>(e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.</p> <p>Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations</p> <p>(a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR</p> <p>(b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.</p> <p>The following information must be provided by the prescriber at the time of application</p> <p>(a) The patient's International Prognostic Scoring System (IPSS) score.</p> <p>The following reports must be documented in the patient's medical records</p> <p>(a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and</p> <p>(b) full blood examination report; and</p> <p>(c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).</p> <p>No more than 3 cycles will be authorised under this restriction in a patient's lifetime.</p>	
C13268	P13268	CN13268	Vismodegib	<p>Metastatic or locally advanced basal cell carcinoma (BCC)</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p>	<p>Compliance with Written Authority Required procedures</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The condition must remain inappropriate for surgery; AND The condition must remain inappropriate for curative radiotherapy; AND Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) Confirmation from the treating doctor that the disease has not progressed; and (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy. The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Inappropriate for surgery is defined as (i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or (ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or (iii) Medical contraindication to surgery.</p>	

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				<p>(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</p> <p>(ii) Limitations due to location of tumour; or</p> <p>(iii) Limitations due to cumulative prior radiotherapy dose; or</p> <p>(iv) Progressive disease despite prior irradiation of locally advanced BCC.</p> <p>Inappropriate for curative radiotherapy is defined as</p> <p>(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</p> <p>(ii) Limitations due to location of tumour; or</p> <p>(iii) Limitations due to cumulative prior radiotherapy dose; or</p> <p>(iv) Progressive disease despite prior irradiation of locally advanced BCC.</p> <p>For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.</p>	
C13270	P13270	CN13270	Nusinersen	<p>Spinal muscular atrophy (SMA)</p> <p>Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug;</p> <p>Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood;</p> <p>Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised);</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or</p>	Compliance with Written Authority Required procedures

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				<p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); or</p> <p>Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are</p> <p>(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,</p> <p>(ii) Proximal weakness,</p> <p>(iii) Hypotonia,</p> <p>(iv) Absence of deep tendon reflexes,</p> <p>(v) Failure to gain weight appropriate for age,</p> <p>(vi) Any active denervation or chronic neurogenic changes found on electromyography,</p> <p>(vii) A compound muscle action potential below normative values for an age-matched child.</p> <p>In this authority application, confirm</p> <p>(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,</p>	

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				(2) which of the above (i to vii) (at least 1) were present during childhood, (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.	
C13276	P13276	CN13276	Entrectinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
C13282	P13282	CN13282	Somatrogon	Short stature and slow growth Recommencement of treatment as a reclassified patient Patient must be undergoing treatment that is simultaneously: (a) recommencing treatment following a temporary break in treatment (i.e. a lapse), plus (b) reclassifying the PBS indication whilst continuing with the same growth hormone; subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication where the most recent authority approval was for a different growth hormone; AND Patient must have had a lapse in growth hormone treatment; AND The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND Patient must have had a height no higher than the 1 st percentile for age plus sex at the time treatment first commenced; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had a growth velocity below the 25th percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; or</p> <p>Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7 cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>1. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of</p>	

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				<p>treatment where the patient had a chronological age greater than 2.5 years at commencement of treatment.</p> <p>2. Recent growth data (height and weight, not older than three months).</p> <p>3. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13284	P13284	CN13284	Somatrogen	<p>Short stature and slow growth</p> <p>Initial treatment</p> <p>Patient must have a current height at or below the 1st percentile for age and sex; AND</p> <p>Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or</p> <p>Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7 cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND</p> <p>Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; or</p> <p>Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm; AND</p> <p>Must be treated by a specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:</p> <ol style="list-style-type: none"> 1. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. 3. Confirmation of the patient's maturational or constitutional delay status. 4. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile. 	

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				<p>If the application is submitted through HPOS form upload or mail, it must include</p> <ul style="list-style-type: none"> (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13287	P13287	CN13287	Somatrogen	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Continuing treatment as a reclassified patient</p> <p>Patient must be undergoing continuing PBS-subsidised therapy with this drug where the most recent authority approval for this drug was for a different PBS indication to that stated above - subsidy through this treatment phase must not:</p> <ul style="list-style-type: none"> (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication where the most recent authority approval was for a different growth hormone, (v) reclassify the PBS indication and recommence treatment simultaneously; AND <p>The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following:</p> <ul style="list-style-type: none"> (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency</p>	

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				<p>either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR</p> <p>(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age plus sex immediately prior to commencing treatment.</p> <p>2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations.</p> <p>3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.</p> <p>4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13288	P13288	CN13288	Somatrogen Somatropin	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Change of drug</p> <p>Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy</p>	Compliance with Authority Required procedures

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				<p>through this treatment phase must not:</p> <p>(i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication; AND</p> <p>Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; or</p> <p>Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; or</p> <p>Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of:</p> <p>(i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range); AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>Definition</p> <p>An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of</p> <p>(a) the 50th percentile growth velocity for bone age;</p> <p>(b) an increase in height standard deviation score for chronological age;</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(c) a minimum growth velocity of 4 cm per year; (d) a mid-parental height standard deviation score. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none"> 1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. <p>Where growth data has been supplied within 3 months of this authority application, do not resupply this data. If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none"> (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13290	P13290	CN13290	Avelumab	<p>Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13290</p>

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				The treatment must be the sole PBS-subsidised therapy for this condition.	
C13292	P13292	CN13292	Somatrogen	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Initial treatment</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND</p> <p>Patient must have a current height at or below the 1st percentile for age and sex; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or</p> <p>Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; or</p> <p>Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:</p> <p>1. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; or</p>	

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				<p>(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex.</p> <p>2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.</p> <p>3. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13293	P13293	CN13293	Mecasermin	<p>Severe growth failure with primary insulin-like growth factor-1 deficiency</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have a bone age of less than 13.5 years (females); or</p> <p>Patient must have a bone age of less than 15.5 years (males); AND</p> <p>The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing); AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must be responsive to this drug treatment as evidenced by each of: (i) patient is showing catch-up for height standard deviation score against Laron syndrome (growth hormone insensitivity syndrome) growth charts, (ii) patient has a growth velocity of greater than 2 cm per year (extrapolated for time on treatment) at the time of this continuing authority application; or</p> <p>The condition must be yet to respond to this drug treatment only for the reason of sub-optimal dosing; AND</p> <p>Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; or</p> <p>Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician; Patient must be aged from 2 years up until their 18th birthday.</p> <p>The continuing treatment authority application must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) The patient's height (cm);</p> <p>(2) Where this authority application seeks to continue treatment where there has been an inadequate response to treatment due to sub-optimal dosing, state each of</p> <p>(i) the most recently prescribed dose (mg/kg) that resulted in an inadequate response;</p> <p>(ii) the dose (mg/kg) (between 0.04 to 0.12) that was/will be subsequently prescribed to address the inadequate response;</p> <p>(3) The patient's weight (kg);</p> <p>(4) The patient's growth velocity in response to the preceding supply of drug (cm/year; extrapolated for time on treatment);</p> <p>(5) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.</p> <p>Height, growth velocity and weight measurements must not be more than three months old at the time of application.</p> <p>Document growth improvements in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p>	

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				(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C13294	P13294	CN13294	Somatrogen	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must be undergoing privately funded treatment (e.g. through a clinical trial, a sponsor compassionate access program, supply from an overseas jurisdiction) with this drug at the time of this authority application - subsidy through this treatment phase must only occur once per lifetime; AND</p> <p>The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following:</p> <p>(i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND</p> <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p>	

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				<p>Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none"> 1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age plus sex immediately prior to commencing treatment. 2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations. 3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none"> (i) A completed authority prescription form; and 	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13297	P13297	CN13297	Somatrogen	<p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature associated with biochemical growth hormone deficiency</p> <p>Recommencement of treatment</p> <p>Patient must be undergoing recommencing treatment following a temporary treatment break (i.e. a lapse) from this drug for the stated indication above - subsidy through this treatment phase must not:</p> <p>(i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication; AND</p> <p>Patient must have had a lapse in growth hormone treatment; AND</p> <p>The treatment must not be for the purposes of resuming treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following:</p> <p>(i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none">1. Recent growth data (height and weight, not older than three months).2. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none">(i) A completed authority prescription form; and(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13298	P13298	CN13298	Somatrogen	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Recommencement of treatment as a reclassified patient</p> <p>Patient must be undergoing treatment that is simultaneously:</p> <p>(a) recommencing treatment following a temporary break in treatment (i.e. a lapse), plus (b) reclassifying the PBS indication whilst continuing with the same growth hormone; subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication where the most recent authority approval was for a different growth hormone; AND</p> <p>Patient must have had a lapse in growth hormone treatment; AND</p> <p>The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following:</p> <p>(i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND</p> <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none"> 1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age plus sex immediately prior to commencing treatment. 2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations. 3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none"> (i) A completed authority prescription form; and 	

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				<p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13304	P13304	CN13304	Somatrogen	<p>Short stature and slow growth</p> <p>Recommencement of treatment</p> <p>Patient must be undergoing recommencing treatment following a temporary treatment break (i.e. a lapse) from this drug for the stated indication above - subsidy through this treatment phase must not:</p> <p>(i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication; AND</p> <p>Patient must have had a lapse in growth hormone treatment; AND</p> <p>The treatment must not be for the purposes of resuming treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following:</p> <p>(i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be male and must not have a height greater than or equal to 167.7cm; or Patient must be female and must not have a height greater than or equal to 155.0cm; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none"> 1. Recent growth data (height and weight, not older than three months). 2. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none"> (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p>	

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C13308	P13308	CN13308	Somatrogen	<p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature and slow growth</p> <p>Continuing treatment</p> <p>Patient must be undergoing continuing PBS-subsidised therapy with this drug - subsidy through this treatment phase must not:</p> <p>(i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication; AND</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category; AND</p> <p>Patient must have achieved the 50th percentile growth velocity for bone age plus sex following the most recent supply; or</p> <p>Patient must have achieved an increase in height standard deviation score for chronological age plus sex following the most recent supply; or</p> <p>Patient must have achieved a minimum growth velocity of 4 cm per year following the most recent supply; or</p> <p>Patient must have achieved a mid-parental height standard deviation score following the most recent supply; or</p> <p>The treatment must have been administered at a dose that is lower than that recommended in the approved Product Information in the most recent supply; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0cm; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none"> 1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. 3. The final adult height (in cm) of the patient's mother and father (where available). <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none"> (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13309	P13309	CN13309	Somatrogon Somatropin	<p>Short stature and slow growth</p> <p>Change of drug</p> <p>Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not:</p> <ol style="list-style-type: none"> (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication; <p>AND</p> <p>Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; or</p>	Compliance with Authority Required procedures

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				<p>Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; or</p> <p>Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of:</p> <p>(i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range); AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0cm; AND</p> <p>Must be treated by a specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>Definition</p> <p>An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of</p> <p>(a) the 50th percentile growth velocity for bone age;</p> <p>(b) an increase in height standard deviation score for chronological age;</p> <p>(c) a minimum growth velocity of 4 cm per year;</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(d) a mid-parental height standard deviation score.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none"> 1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. <p>Where growth data has been supplied within 3 months of this authority application, do not resupply this data.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none"> (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13311	P13311	CN13311	Somatrogen	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Continuing treatment</p> <p>Patient must be undergoing continuing PBS-subsidised therapy with this drug - subsidy through this treatment phase must not:</p> <ol style="list-style-type: none"> (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication; AND <p>Patient must have achieved the 50th percentile growth velocity for bone age plus sex following the most recent supply; or</p>	<p>Compliance with Authority Required procedures</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have achieved an increase in height standard deviation score for chronological age plus sex following the most recent supply; or</p> <p>Patient must have achieved a minimum growth velocity of 4 cm per year following the most recent supply; or</p> <p>Patient must have achieved a mid-parental height standard deviation score following the most recent supply; or</p> <p>The treatment must have been administered at a dose that is lower than that recommended in the approved Product Information in the most recent supply; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none">1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.3. The final adult height (in cm) of the patient's mother and father (where available). <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none">(i) A completed authority prescription form; and(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13312	P13312	CN13312	Somatrogen	<p>Short stature and slow growth</p> <p>Continuing treatment as a reclassified patient</p> <p>Patient must be undergoing continuing PBS-subsidised therapy with this drug where the most recent authority approval for this drug was for a different PBS indication to that stated above - subsidy through this treatment phase must not:</p> <p>(i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication where the most recent authority approval was for a different growth hormone, (v) reclassify the PBS indication and recommence treatment simultaneously; AND</p> <p>The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following:</p> <p>(i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND</p> <p>Patient must have had a height no higher than the 1st percentile for age plus sex at the time treatment first commenced; AND</p> <p>Patient must have had a growth velocity below the 25th percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; or</p> <p>Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be male and must not have a height greater than or equal to 167.7cm; or Patient must be female and must not have a height greater than or equal to 155.0cm; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none"> 1. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where the patient had a chronological age greater than 2.5 years at commencement of treatment. 2. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months. 3. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years. <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ol style="list-style-type: none"> (i) A completed authority prescription form; and 	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13313	P13313	CN13313	Avelumab	<p>Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer Maintenance therapy - Initial treatment Patient must have received first-line platinum-based chemotherapy; AND Patient must not have progressive disease following first-line platinum-based chemotherapy; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13313
C13318	P13318	CN13318	Somatrogon	<p>Short stature and slow growth Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be undergoing privately funded treatment (e.g. through a clinical trial, a sponsor compassionate access program, supply from an overseas jurisdiction) with this drug at the time of this authority application - subsidy through this treatment phase must only occur once per lifetime; AND The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family</p>	Compliance with Authority Required procedures

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				<p>problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND</p> <p>Patient must have had a height no higher than the 1st percentile for age plus sex at the time treatment first commenced; AND</p> <p>Patient must have had a growth velocity below the 25th percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; or</p> <p>Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7 cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment; OR</p> <p>(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age plus sex immediately prior to commencing treatment.</p> <p>2. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.</p> <p>3. A bone age result performed within the last 12 months where the patient has chronological age greater than 2.5 years.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13320	P13320	CN13320	Mecasermin	<p>Severe growth failure with primary insulin-like growth factor-1 deficiency</p> <p>Initial treatment</p> <p>The condition must be caused by severe primary insulin-like growth factor-1 deficiency (IGFD), with IGFD deficiency for the purpose of PBS subsidy defined as a basal IGF-1 level (measured any time prior to initiating treatment with this drug) below the 2.5th percentile adjusted for each of:</p> <p>(i) age, (ii) gender; AND</p> <p>The condition must have resulted in the patient experiencing short stature, with short stature for the purpose of PBS subsidy defined as the patient's height (measured</p>	Compliance with Authority Required procedures

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				<p>any time prior to initiating treatment with this drug) being at least 3 standard deviations below the norm, adjusted for each of:</p> <p>(i) age, (ii) gender; AND</p> <p>Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); AND</p> <p>The condition must not be caused by growth hormone deficiency; AND</p> <p>Patient must have a bone age of less than 13.5 years (females); or</p> <p>Patient must have a bone age of less than 15.5 years (males); AND</p> <p>The condition must not be caused by secondary causes of IGFD - prior to initiating treatment with this drug, the treating physician has at least excluded each of the following:</p> <p>(i) malnutrition, (ii) hypopituitarism, (iii) hypothyroidism, (iv) medication side effects; AND</p> <p>The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing); AND</p> <p>Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; or</p> <p>Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician;</p> <p>Patient must be aged from 2 years up until their 18th birthday.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>The initial treatment authority application must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include the following</p> <p>(1) Insulin-like growth factor-1 deficiency</p> <p>(2) Short stature</p> <p>(3) Normal growth hormone levels</p> <p>(4) Bone age (where the patient has a chronological age of at least 2.5 years):</p> <p>(5) The patient's weight (kg);</p> <p>(6) The prescribed dose (mg/kg) (between 0.04 to 0.12);</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.</p> <p>State each of (a) the patient's most recent basal IGF-1 level measured (ng/mL), (b) the measurement date (dd/mm/yy), (c) the name of the pathology result provider;</p> <p>(2) Short stature</p> <p>(3) Normal growth hormone levels</p> <p>(4) Bone age (where the patient has a chronological age of at least 2.5 years):</p> <p>(5) The patient's weight (kg);</p> <p>(6) The prescribed dose (mg/kg) (between 0.04 to 0.12);</p> <p>(7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.</p> <p>State the patient's height (cm);</p> <p>(3) Normal growth hormone levels</p> <p>(4) Bone age (where the patient has a chronological age of at least 2.5 years):</p> <p>(5) The patient's weight (kg);</p> <p>(6) The prescribed dose (mg/kg) (between 0.04 to 0.12);</p> <p>(7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.</p> <p>State the patient's most recent growth hormone level measurement (mcg/L) - this figure must be greater than 6.6 mcg/L;</p> <p>(4) Bone age (where the patient has a chronological age of at least 2.5 years):</p> <p>(5) The patient's weight (kg);</p> <p>(6) The prescribed dose (mg/kg) (between 0.04 to 0.12);</p> <p>(7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.</p> <p>State each of (a) the patient's bone age in numerical figures at the time when it was most recently determined, (b) the date (dd/mm/yy) of this determination that is within 12 months of this authority application;</p> <p>(5) The patient's weight (kg);</p>	

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C13321	P13321	CN13321	Trientine	<p>(6) The prescribed dose (mg/kg) (between 0.04 to 0.12);</p> <p>(7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.</p> <p>Height, growth velocity and weight measurements must not be more than three months old at the time of application.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Chelation of elevated copper levels</p> <p>Patient must have a diagnosis of Wilson disease; AND</p> <p>Patient must be intolerant to penicillamine; AND</p> <p>Must be treated by a specialist medical practitioner, where this authority application is to initiate treatment with this drug, of the following type:</p> <p>(i) gastroenterologist, (ii) hepatologist, (iii) neurologist; the authority prescription must be completed by the specialist prescriber. or</p> <p>Must be treated by a medical practitioner (of any type), where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types. or</p> <p>Must be treated by a nurse practitioner where this authority application is continuing established trientine treatment (of any specified salt) initiated by one of the above mentioned specialist types.</p> <p>Prior to seeking the initial authority approval, establish evidence of excess copper levels based on at least one of (i) clinical symptoms, (ii) measured serum copper levels, (iii) measured urinary copper levels.</p> <p>Document what these findings were in the patient's medical records. Do not supply them in this authority application.</p> <p>Refer to the following definitions if in doubt over what constitutes an acceptable intolerance to penicillamine</p> <p>Side effects of penicillamine occurring soon after initiation (within first few weeks/months)</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) fever, (ii) rash, (iii) enlarged lymph nodes, (iv) neutropenia, (v) thrombocytopenia, (vi) proteinuria, (vii) severe, persistent nausea.</p> <p>(i) nephrotic syndrome, (ii) glomerulonephritis, (iii) total bone marrow aplasia, (iv) skin changes (cutis laxa, elastosis perforans serpiginosa, pemphigus), (v) myasthenia gravis, (vi) polymyositis, (vii) Goodpasture syndrome, (viii) optic neuritis, (ix) proteinuria (1-2 grams/day or equivalent in children, depending on specialist Wilson disease and renal review), (x) haematuria (if cause unknown), (xi) thrombocytopenia/leukopenia, (xii) bleeding related to thrombocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia.</p> <p>Side effects of penicillamine developing later</p> <p>(i) nephrotic syndrome, (ii) glomerulonephritis, (iii) total bone marrow aplasia, (iv) skin changes (cutis laxa, elastosis perforans serpiginosa, pemphigus), (v) myasthenia gravis, (vi) polymyositis, (vii) Goodpasture syndrome, (viii) optic neuritis, (ix) proteinuria (1-2 grams/day or equivalent in children, depending on specialist Wilson disease and renal review), (x) haematuria (if cause unknown), (xi) thrombocytopenia/leukopenia, (xii) bleeding related to thrombocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia.</p> <p>At the time of the first authority application for this drug, document the details (date of reaction, severity of reaction, dose of penicillamine, etc) of the penicillamine intolerance, if not already done, in the patient's medical records. Do not supply these details in this authority application.</p>	
C13322	P13322	CN13322	Cemiplimab	<p>Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised therapy with this drug for this condition prior to 1 November 2022; AND</p> <p>The condition must be unsuitable for each of:</p> <p>(i) curative surgical resection, (ii) curative radiotherapy; AND</p> <p>Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first:</p>	Compliance with Authority Required procedures

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				(i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	
C13327	P13327	CN13327	Eltrombopag	<p>Severe thrombocytopenia</p> <p>Second or Subsequent Continuing treatment</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction; AND</p> <p>Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures
C13330	P13330	CN13330	Burosumab	<p>X-linked hypophosphataemia</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved normalisation in serum phosphate levels; AND</p> <p>Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion; AND</p> <p>Must be treated by a medical practitioner identifying as at least one of the following specialists:</p> <p>(i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.</p> <p>Where adequate response to treatment with this drug cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug,</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p>	
C13336	P13336	CN13336	Aflibercept Dexamethasone Ranibizumab	<p>Central retinal vein occlusion with macular oedema</p> <p>Continuing treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13336
C13337	P13337	CN13337	Aflibercept Ranibizumab	<p>Subfoveal choroidal neovascularisation (CNV)</p> <p>Initial treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>The condition must be due to pathologic myopia (PM); AND</p> <p>The condition must be diagnosed by optical coherence tomography; or</p> <p>The condition must be diagnosed by fluorescein angiography; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Authority approval for initial treatment of each eye must be sought.</p> <p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p>	Compliance with Written Authority Required procedures

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				(a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.	
C13340	P13340	CN13340	Ranibizumab	Subfoveal choroidal neovascularisation (CNV) Continuing treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must not be due to pathologic myopia; AND The condition must not be due to age-related macular degeneration; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	Compliance with Authority Required procedures - Streamlined Authority Code 13340
C13341	P13341	CN13341	Dexamethasone	Diabetic macular oedema (DMO) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have visual impairment due to diabetic macular oedema; AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND Patient must have had a cataract removed in the treated eye; or Patient must be scheduled for cataract surgery in the treated eye; AND Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; or Patient must be unsuitable for treatment with VEGF inhibitors; or Patient must have failed prior treatment with VEGF inhibitors; AND	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be as monotherapy; or The treatment must be in combination with laser photocoagulation; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p>	
C13346	P13346	CN13346	Somatropin	<p>Short stature associated with biochemical growth hormone deficiency Initial treatment</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test</p>	Compliance with Authority Required procedures

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				<p>(pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND</p> <p>Patient must have a current height at or below the 1st percentile for age and sex; or</p> <p>Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or</p> <p>Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; or</p> <p>Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND 3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 	

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C13350	P13350	CN13350	Somatropin	<p>6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature and slow growth</p> <p>Continuing treatment</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category; AND</p> <p>Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0cm; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND 3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 5. The final adult height (in cm) of the patient's mother and father (where available); AND 	

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C13352	P13352	CN13352	Somatropin	<p>6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature and slow growth Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category; AND Patient must have had a lapse in growth hormone treatment; AND The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0cm; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND 3. Recent growth data (height and weight, not older than three months); AND 	

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C13353	P13353	CN13353	Somatropin	<p>4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND</p> <p>5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature associated with biochemical growth hormone deficiency</p> <p>Recommencement of treatment as a reclassified patient</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency; AND</p> <p>Patient must have had a lapse in treatment; AND</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); or</p> <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p>	

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				<p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR (c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. Recent growth data (height and weight, not older than three months); AND 	

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C13355	P13355	CN13355	Somatropin	<p>6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND</p> <p>7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature and slow growth</p> <p>Recommencement of treatment as a reclassified patient</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth; AND</p> <p>Patient must have had a lapse in treatment; AND</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; or</p> <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both:</p> <p>(i) a height no higher than the 1st percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7 cm; or</p>	

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none">1. A completed authority prescription form; AND2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR (b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND</p> <p>4. Recent growth data (height and weight, not older than three months); AND</p> <p>5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND</p> <p>6. The proprietary name (brand), form and strength of the growth hormone requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13356	P13356	CN13356	Somatropin	<p>Short stature and slow growth</p> <p>Initial treatment</p> <p>Patient must have a current height at or below the 1st percentile for age and sex; AND</p> <p>Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or</p> <p>Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p>	Compliance with Authority Required procedures

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Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be male and must not have a height greater than or equal to 167.7 cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND</p> <p>Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; or</p> <p>Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm; AND</p> <p>Must be treated by a specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND 3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 5. Confirmation of the patient's maturational or constitutional delay status; AND 	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13359	P13359	CN13359	Somatropin	<p>6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND</p> <p>7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature and slow growth</p> <p>Continuing treatment as a reclassified patient</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth; AND</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; or</p> <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both:</p> <p>(i) a height no higher than the 1st percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Patient must be male and must not have a height greater than or equal to 167.7cm; or</p> <p>Patient must be female and must not have a height greater than or equal to 155.0cm; AND</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR (b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND 4. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND 	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13360	P13360	CN13360	Somatropin	<p>5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND</p> <p>6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature associated with biochemical growth hormone deficiency</p> <p>Recommencement of treatment</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category; AND</p> <p>Patient must have had a lapse in growth hormone treatment; AND</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND 3. Recent growth data (height and weight, not older than three months); AND 	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13363	P13363	CN13363	Somatropin	<p>4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND</p> <p>5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature associated with biochemical growth hormone deficiency</p> <p>Continuing treatment</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category; AND</p> <p>Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND 3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 5. The final adult height (in cm) of the patient's mother and father (where available); AND 6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed). 	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13364	P13364	CN13364	Somatropin	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Continuing treatment as a reclassified patient</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency; AND</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); or</p> <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test</p>	

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR (c) Confirmation that the patient has previously received treatment under the indication <i>risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants</i> and has reached or surpassed 5 years of age (chronological); AND 4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND 6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed). <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in</p>	

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				<p>compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13367	P13367	CN13367	Somatropin	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Initial treatment</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test</p> <p>(pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; AND</p> <p>Patient must have a current height at or below the 1st percentile for age and sex; or</p> <p>Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or</p> <p>Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements</p>	

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C13368	P13368	CN13368	Somatropin	<p>detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND 3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND 4. A bone age result performed within the last 12 months; AND 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND 6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed). <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature associated with biochemical growth hormone deficiency Recommencement of treatment</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category; AND</p> <p>Patient must have had a lapse in growth hormone treatment; AND</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p>	

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				<p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND 3. Recent growth data (height and weight, not older than three months); AND 4. A bone age result performed within the last 12 months; AND 5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed). <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13377	P13377	CN13377	Burosumab	<p>X-linked hypophosphataemia</p> <p>Initial treatment - New patient</p> <p>Patient must have a documented confirmation of PHEX pathogenic variant; or</p> <p>Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following:</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13378	P13378	CN13378	Nintedanib Pirfenidone	<p>(i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine; AND</p> <p>Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p> <p>Idiopathic pulmonary fibrosis Initial treatment 1 - new patient The condition must be diagnosed through a multidisciplinary team; AND Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months; AND Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height; AND Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND Patient must not have had an acute respiratory infection at the time of FVC measurement; AND Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Must be treated by a medical practitioner who is either:</p> <ul style="list-style-type: none">(i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND <p>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications:</p> <ul style="list-style-type: none">(i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND <p>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:</p> <ul style="list-style-type: none">(i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND <p>Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following:</p> <ul style="list-style-type: none">(i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement. <p>A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.</p> <p>Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.</p> <p>Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ul style="list-style-type: none">(a) a completed authority prescription form; and(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13380	P13380	CN13380	Nintedanib Pirfenidone	<p>Idiopathic pulmonary fibrosis</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND</p> <p>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND</p> <p>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.</p>	Compliance with Authority Required procedures
C13381	P13381	CN13381	Nintedanib Pirfenidone	<p>Idiopathic pulmonary fibrosis</p> <p>Initial treatment 2 - change or recommencement of treatment</p> <p>Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND</p> <p>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND</p> <p>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.</p>	Compliance with Authority Required procedures
C13384	P13384	CN13384	Aflibercept Ranibizumab	<p>Branch retinal vein occlusion with macular oedema</p> <p>Initial treatment</p>	Compliance with Written Authority Required procedures

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				<p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO); AND</p> <p>Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment; AND</p> <p>The condition must be diagnosed by optical coherence tomography; or</p> <p>The condition must be diagnosed by fluorescein angiography; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Authority approval for initial treatment of each eye must be sought.</p> <p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p>	
C13387	P13387	CN13387	<p>Aflibercept</p> <p>Dexamethasone</p> <p>Ranibizumab</p>	<p>Branch retinal vein occlusion with macular oedema</p> <p>Continuing treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13387</p>

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				The treatment must be the sole PBS-subsidised therapy for this condition.	
C13388	P13388	CN13388	Aflibercept Faricimab Ranibizumab	<p>Diabetic macular oedema (DMO) Initial treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>Patient must have visual impairment due to diabetic macular oedema; AND</p> <p>Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND</p> <p>The condition must be diagnosed by optical coherence tomography; or</p> <p>The condition must be diagnosed by fluorescein angiography; AND</p> <p>The treatment must be as monotherapy; or</p> <p>The treatment must be in combination with laser photocoagulation; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Authority approval for initial treatment of each eye must be sought.</p> <p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p>	Compliance with Written Authority Required procedures

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C13390	P13390	CN13390	Aflibercept Ranibizumab	<p>Central retinal vein occlusion with macular oedema Initial treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); AND</p> <p>Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment; AND</p> <p>The condition must be diagnosed by optical coherence tomography; or</p> <p>The condition must be diagnosed by fluorescein angiography; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Authority approval for initial treatment of each eye must be sought.</p> <p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p>	Compliance with Written Authority Required procedures
C13392	P13392	CN13392	Aflibercept Ranibizumab	<p>Subfoveal choroidal neovascularisation (CNV) Continuing treatment</p>	Compliance with Authority Required procedures -

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				Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to pathologic myopia (PM); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.	Streamlined Authority Code 13392
C13393	P13393	CN13393	Somatropin	Short stature associated with biochemical growth hormone deficiency Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category; AND Patient must not have been on the maximum dose of 7.5mg/m ² /week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m ² /week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m ² /week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m ² /week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m ² /week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include</p> <ol style="list-style-type: none">1. A completed authority prescription form; AND2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND4. A bone age result performed within the last 12 months; AND5. The final adult height (in cm) of the patient's mother and father (where available); AND6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed). <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13396	P13396	CN13396	Romiplostim	<p>Severe thrombocytopenia</p> <p>Second or Subsequent Continuing treatment</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction; AND</p> <p>Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p> <p>The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.</p> <p>Authority approval will not be given for doses higher than 10 micrograms/kg/week</p>	Compliance with Authority Required procedures
C13400	P13400	CN13400	Burosumab	<p>X-linked hypophosphataemia</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2022; AND</p> <p>Patient must have a documented confirmation of PHEX pathogenic variant; or</p> <p>Patient must have, prior to commencing non-PBS-subsidised supply, a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following:</p> <ul style="list-style-type: none"> (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine; AND 	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have achieved normalisation in serum phosphate levels; AND Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion; AND Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist. Where adequate response to treatment with this drug cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p>	
C13401	P13401	CN13401	Nintedanib	<p>Progressive fibrosing Interstitial lung disease Initial treatment The condition must be diagnosed through a multidisciplinary team; AND The condition must have chest imaging through high resolution computed tomography (HRCT) that is no older than 12 months, to support the diagnosis of the PBS indication; AND The condition must display, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5); AND Patient must have a current (no older than 2 years) forced vital capacity (FVC) measurement of no less than 45% predicted, adjusted for each of: (i) age, (ii) gender, (iii) height; AND The condition must be of a progressive nature, observed by, in the 2 years leading up to this authority application, any of: (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records; AND</p> <p>Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND</p> <p>Patient must not have had an acute respiratory infection at the time of FVC measurement; AND</p> <p>Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that is both:</p> <p>(i) at least 30% predicted, (ii) no greater than 80% predicted; AND</p> <p>The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is); AND</p> <p>The condition must not be due to reversible causes (e.g. drug toxicity); AND</p> <p>Must be treated by a medical practitioner who is either:</p> <p>(i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND</p> <p>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications:</p> <p>(i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND</p> <p>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:</p> <p>(i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following:</p> <p>(i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.</p> <p>Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)</p> <p>A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.</p> <p>Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.</p>	
C13402	P13402	CN13402	Aflibercept Faricimab Ranibizumab	<p>Diabetic macular oedema (DMO)</p> <p>Continuing treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND</p> <p>The treatment must be as monotherapy; or</p> <p>The treatment must be in combination with laser photocoagulation; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13402
C13406	P13406	CN13406	Aflibercept Faricimab Ranibizumab	<p>Subfoveal choroidal neovascularisation (CNV)</p> <p>Continuing treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>The condition must be due to age-related macular degeneration (AMD); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13406
C13411	P13411	CN13411	Cemiplimab	<p>Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first:</p> <p>(i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.</p>	
C13412	P13412	CN13412	Nintedanib	<p>Progressive fibrosing Interstitial lung disease</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Must be treated by a medical practitioner who is either:</p> <p>(i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND</p> <p>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications:</p> <p>(i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND</p> <p>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:</p> <p>(i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.</p>	Compliance with Authority Required procedures
C13417	P13417	CN13417	Somatropin	<p>Short stature associated with biochemical growth hormone deficiency</p> <p>Continuing treatment as a reclassified patient</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency; AND</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); or</p> <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND</p> <p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p>	

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				<p>Patient must not have an active tumour or evidence of tumour growth or activity; AND Patient must be male and must not have a bone age of 15.5 years or more; or Patient must be female and must not have a bone age of 13.5 years or more; AND Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include 1. A completed authority prescription form; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13418	P13418	CN13418	Somatropin	<p>(c) Confirmation that the patient has previously received treatment under the indication <i>risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants</i> and has reached or surpassed 5 years of age (chronological); AND</p> <p>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND</p> <p>5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND</p> <p>6. A bone age result performed within the last 12 months; AND</p> <p>7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p> <p>Short stature associated with biochemical growth hormone deficiency</p> <p>Recommencement of treatment as a reclassified patient</p> <p>Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency; AND</p> <p>Patient must have had a lapse in treatment; AND</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or</p> <p>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND</p> <p>Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); or</p> <p>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or</p> <p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or</p> <p>Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; AND</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND</p> <p>Patient must not have an active tumour or evidence of tumour growth or activity; AND</p> <p>Patient must be male and must not have a bone age of 15.5 years or more; or</p> <p>Patient must be female and must not have a bone age of 13.5 years or more; AND</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or</p> <p>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND</p> <p>Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.</p> <p>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.</p> <p>The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the <i>National Health (Growth Hormone Program) Special Arrangement 2015</i> and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>The authority application must be in writing and must include</p> <ol style="list-style-type: none">1. A completed authority prescription form; AND2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR</p> <p>(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND</p> <p>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND</p> <p>5. Recent growth data (height and weight, not older than three months); AND</p> <p>6. A bone age result performed within the last 12 months; AND</p> <p>7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).</p> <p>Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.</p> <p>Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.</p> <p>In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.</p>	
C13419	P13419	CN13419	Cemiplimab	<p>Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)</p> <p>Initial treatment covering the first 3 treatment cycles</p> <p>The condition must be unsuitable for each of:</p> <p>(i) curative surgical resection, (ii) curative radiotherapy; AND</p> <p>Patient must have had a WHO performance status of 0 or 1; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p>	Compliance with Authority Required procedures
C13422	P13422	CN13422	Ranibizumab	<p>Subfoveal choroidal neovascularisation (CNV)</p> <p>Initial treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p>	Compliance with Written Authority Required procedures

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				<p>The condition must be due to age-related macular degeneration (AMD); AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.</p>	
C13423	P13423	CN13423	Dexamethasone	<p>Central retinal vein occlusion with macular oedema Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; or</p> <p>Patient must have failed prior treatment with VEGF inhibitors; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Authority approval for initial treatment of each eye must be sought.</p> <p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p>	
C13424	P13424	CN13424	Aflibercept Faricimab	<p>Subfoveal choroidal neovascularisation (CNV)</p> <p>Initial treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>The condition must be due to age-related macular degeneration (AMD); AND</p> <p>The condition must be diagnosed by optical coherence tomography; or</p> <p>The condition must be diagnosed by fluorescein angiography; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Authority approval for initial treatment of each eye must be sought.</p> <p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p>	Compliance with Written Authority Required procedures

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				<p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p>	
C13426	P13426	CN13426	Brolucizumab	<p>Subfoveal choroidal neovascularisation (CNV)</p> <p>Continuing treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>The condition must be due to age-related macular degeneration (AMD); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.</p>	Compliance with Authority Required procedures
C13427	P13427	CN13427	Ranibizumab	<p>Subfoveal choroidal neovascularisation (CNV)</p> <p>Initial treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>The condition must not be due to pathologic myopia; AND</p> <p>The condition must not be due to age-related macular degeneration; AND</p> <p>The condition must be diagnosed by optical coherence tomography; or</p> <p>The condition must be diagnosed by fluorescein angiography; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Authority approval for initial treatment of each eye must be sought.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p>	
C13428	P13428	CN13428	Dexamethasone	<p>Diabetic macular oedema (DMO)</p> <p>Continuing treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>Patient must have had a cataract removed in the treated eye; or</p> <p>Patient must be scheduled for cataract surgery in the treated eye; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND</p> <p>The treatment must be as monotherapy; or</p> <p>The treatment must be in combination with laser photocoagulation; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13428
C13429	P13429	CN13429	Dexamethasone	<p>Branch retinal vein occlusion with macular oedema</p> <p>Initial treatment</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO); AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment; AND</p> <p>The condition must be diagnosed by optical coherence tomography; or</p> <p>The condition must be diagnosed by fluorescein angiography; AND</p> <p>Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; or</p> <p>Patient must have failed prior treatment with VEGF inhibitors; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Authority approval for initial treatment of each eye must be sought.</p> <p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p>	
C13431	P13431	CN13431	Pembrolizumab	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Initial treatment - 3 weekly treatment regimen</p> <p>Patient must not have previously been treated for this condition in the metastatic setting; or</p> <p>The condition must have progressed after treatment with tepotinib; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13431</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND</p> <p>The treatment must not exceed a total of 7 doses under this restriction.</p>	
C13432	P13432	CN13432	Pembrolizumab	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Continuing treatment - 3 weekly treatment regimen</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13432
C13433	P13433	CN13433	Nivolumab	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Initial combination treatment (with ipilimumab) as first-line drug therapy</p> <p>The condition must be squamous type non-small cell lung cancer (NSCLC); AND</p> <p>Patient must not have previously been treated for this condition in the metastatic setting; or</p> <p>The condition must have progressed after treatment with tepotinib; AND</p> <p>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND</p> <p>The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND</p> <p>The treatment must be in combination with ipilimumab.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13433

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C13434	P13434	CN13434	Tepotinib	<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must have evidence of MET exon 14 skipping alterations in tumour material.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13434
C13435	P13435	CN13435	Tepotinib	<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2022; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have evidence of MET exon 14 skipping alterations in tumour material.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13435
C13436	P13436	CN13436	Pembrolizumab	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 6 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting; or The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 4 doses under this restriction.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13436
C13437	P13437	CN13437	Pembrolizumab	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment - 6 weekly treatment regimen</p>	Compliance with Authority Required procedures -

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.</p>	Streamlined Authority Code 13437
C13441	P13441	CN13441	Tepotinib	<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13441
C13442	P13442	CN13442	Atezolizumab	<p>Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)</p> <p>1,200 mg administered once every 3 weeks</p> <p>Patient must be both:</p> <p>(i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; or</p> <p>Patient must be continuing existing PBS-subsidised treatment with this drug; or</p> <p>Patient must be both:</p> <p>(i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated;</p> <p>Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; AND</p> <p>The treatment must be for the purpose of adjuvant therapy following all of:</p> <p>(i) surgical resection, (ii) platinum-based chemotherapy; AND</p> <p>The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling:</p> <p>(i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13442

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				<p>The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>Patient must be undergoing treatment that does not occur beyond the following, whichever comes first:</p> <p>(i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.</p>	
C13443	P13443	CN13443	Atezolizumab	<p>Locally advanced or metastatic non-small cell lung cancer</p> <p>Initial treatment - 3 weekly treatment regimen</p> <p>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>The condition must have progressed on or after prior platinum based chemotherapy. or</p> <p>The condition must have progressed after treatment with tepotinib.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13443
C13445	P13445	CN13445	Nivolumab	<p>Locally advanced or metastatic non-small cell lung cancer</p> <p>Initial treatment as second-line drug therapy</p> <p>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND</p> <p>The condition must have progressed on or after prior platinum based chemotherapy. or</p> <p>The condition must have progressed after treatment with tepotinib.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13445

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				The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	
C13446	P13446	CN13446	Atezolizumab	Locally advanced or metastatic non-small cell lung cancer Initial treatment - 4 weekly treatment regimen Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have progressed on or after prior platinum based chemotherapy. or The condition must have progressed after treatment with tepotinib.	Compliance with Authority Required procedures - Streamlined Authority Code 13446
C13448	P13448	CN13448	Atezolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment 1 Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC); AND Patient must not have previously been treated for this condition in the metastatic setting; or The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.	Compliance with Authority Required procedures - Streamlined Authority Code 13448
C13451	P13451	CN13451	Atezolizumab	Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,680 mg administered once every 4 weeks, or 840 mg every 2 weeks	Compliance with Authority Required

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				<p>Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; or Patient must be continuing existing PBS-subsidised treatment with this drug; or Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated; Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; AND The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.</p>	<p>procedures - Streamlined Authority Code 13451</p>
C13458	P13458	CN13458	Eculizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses) Patient must be planning pregnancy; or Patient must be pregnant; AND Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND</p>	<p>Compliance with Authority Required procedures</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must not be in combination with any of (i) ravulizumab, (ii) pegcetacoplan; AND Must be treated by a haematologist. or Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p>	
C13459	P13459	CN13459	Eculizumab Ravulizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised pegcetacoplan - induction doses Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition; AND Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition; AND Patient must have developed resistance or intolerance to pegcetacoplan; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND Must be treated by a haematologist. or Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Authority Required procedures

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C13464	P13464	CN13464	Eculizumab	<p>For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p> <p>Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced clinical improvement as a result of treatment with this drug; or Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; or Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; or Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; or Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; or Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; or</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
C13469	P13469	CN13469	Evolocumab	<p>Familial homozygous hypercholesterolaemia</p> <p>Initial treatment</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>The condition must have been confirmed by genetic testing; or</p>	<p>Compliance with Authority Required procedures</p>

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				<p>The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7; AND</p> <p>Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND</p> <p>Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; or</p> <p>Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; or</p> <p>Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND</p> <p>Must be treated by a specialist physician. or</p> <p>Must be treated by a physician who has consulted a specialist physician.</p> <p>The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.</p> <p>A clinically important product-related adverse event is defined as follows</p> <p>(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or</p> <p>(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or</p> <p>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</p> <p>The following must be stated at the time of application and documented in the patient's medical records</p> <p>(i) the qualifying Dutch Lipid Clinic Network Score; or</p> <p>(ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <p>(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or</p> <p>(ii) the dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or</p> <p>(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information</p>	
C13482	P13482	CN13482	Sildenafil Tadalafil	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p>	Compliance with Authority Required procedures

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				<p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
C13484	P13484	CN13484	Sildenafil Tadalafil	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 (new patients)</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND</p> <p>Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p>	

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C13491	P13491	CN13491	Epoprostenol Iloprost	<p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p> <p>Pulmonary arterial hypertension (PAH) Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, poprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
C13492	P13492	CN13492	Epoprostenol Iloprost	<p>Pulmonary arterial hypertension (PAH)</p> <p>Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy consisting of one endothelin receptor antagonist with one prostanoid, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; or</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND</p> <p>The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; or</p> <p>The condition must have, at the time non-PBS combination therapy was initiated, been both:</p> <p>(i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p>	Compliance with Authority Required procedures

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				<p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13495	P13495	CN13495	Bosentan	<p>- ECHO composite assessment plus 6MWT; - ECHO composite assessment only. (3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>Pulmonary arterial hypertension (PAH) Initial 2 (change) Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction,</p>	Compliance with Authority Required procedures

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C13496	P13496	CN13496	Ambrisentan Bosentan Macitentan	<p>irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.</p> <p>Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.</p> <p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; or</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <ul style="list-style-type: none"> (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function. <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) 	

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				<p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p>	
C13497	P13497	CN13497	Ambrisentan Bosentan Macitentan	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of:</p> <p>(i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of dual combination therapy consisting of:</p> <p>(i) one endothelin receptor antagonist, (ii) one prostanoid; or</p> <p>The treatment must form part of triple combination therapy consisting of:</p> <p>(i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.</p>	
C13499	P13499	CN13499	Ambrisentan Bosentan Macitentan	<p>Pulmonary arterial hypertension (PAH) Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag) The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; or The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.</p>	Compliance with Authority Required procedures
C13500	P13500	CN13500	Ambrisentan Macitentan	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH; AND Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p>	Compliance with Written Authority Required procedures

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				<p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>- RHC composite assessment; and</p> <p>- ECHO composite assessment; and</p> <p>- 6 Minute Walk Test (6MWT)</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
C13502	P13502	CN13502	Riociguat	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p>	<p>Compliance with Authority Required procedures</p>

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				<p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
C13505	P13505	CN13505	Epoprostenol Iloprost	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; or</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; AND</p> <p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
C13506	P13506	CN13506	Epoprostenol Iloprost	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; or</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13510	P13510	CN13510	Epoprostenol Iloprost	<p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Pulmonary arterial hypertension (PAH) Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; or The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; or The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p>	Compliance with Written Authority Required procedures

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				<p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. 	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p>	
C13512	P13512	CN13512	Epoprostenol	<p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures

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				<p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; 	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>- ECHO composite assessment only.</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
C13514	P13514	CN13514	Riociguat	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition.</p> <p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>Swapping between PAH agents:</p> <p>Patients can access PAH agents through the PBS according to the relevant</p>	Compliance with Authority Required procedures

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C13515	P13515	CN13515	Riociguat	<p>restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have been assessed by a physician with expertise in the management of PAH; AND Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition. A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include (a) a completed authority prescription form; and</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. 	

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				<p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.</p> <p>Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p>	
C13518	P13518	CN13518	Infliximab	<p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND</p> <p>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or</p> <p>Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and</p> <p>either</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p>	

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				<p>(1) a completed authority prescription form(s); and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C13526	P13526	CN13526	Infliximab	<p>Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; Patient must be at least 18 years of age; Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; or</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; or</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy. or</p> <p>Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. or</p> <p>Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.</p> <p>Applications for authorisation must be made in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and</p> <p>(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iv) the date of the most recent clinical assessment.</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following</p>	

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				<p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>Evidence of intestinal inflammation includes</p> <p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C13532	P13532	CN13532	Etanercept	<p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND</p> <p>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> <p>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and</p> <p>either</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13533	P13533	CN13533	Etanercept	<p>continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> <p>An adequate response to treatment is defined as</p> <p>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and</p> <p>either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p>	Compliance with Written Authority Required procedures

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				<p>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13538	P13538	CN13538	Etanercept	<p>this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C13556	P13556	CN13556	Adalimumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C13558	P13558	CN13558	Lorlatinib	<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Continuing treatment</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Authority Required procedures
C13560	P13560	CN13560	Eculizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment - initial 1 (new patient) induction doses</p> <p>Patient must not have received prior treatment with this drug for this condition; AND</p> <p>Patient must have a diagnosis of PNH established by flow cytometry; AND</p> <p>Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; or</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; or</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; or</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; or</p> <p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; or</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; or</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <p>(i) Haemoglobin (g/L)</p>	

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				(ii) Platelets (x10 ⁹ /L) (iii) White Cell Count (x10 ⁹ /L) (iv) Reticulocytes (x10 ⁹ /L) (v) Neutrophils (x10 ⁹ /L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH ULN ratio (in figures, rounded to one decimal place) must be at least 1.5	
C13561	P13561	CN13561	Vericiguat	Chronic heart failure Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated. or The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated. or The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.	Compliance with Authority Required procedures - Streamlined Authority Code 13561
C13562	P13562	CN13562	Vericiguat	Chronic heart failure Initial treatment Must be treated by a cardiologist; or Must be treated by a medical practitioner who has been directed to prescribe this medicine by a cardiologist; AND Patient must be symptomatic with NYHA classes II, III or IV; AND	Compliance with Authority Required procedures

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				<p>Patient must have a documented left ventricular ejection fraction (LVEF) of less than 45%; AND</p> <p>The condition must be stabilised following a decompensation event that required at least one of:</p> <p>(i) hospitalisation in the past 6 months, (ii) intravenous diuretic therapy in the past three months; AND</p> <p>Patient must not have clinical signs of fluid overload; AND</p> <p>Patient must not have received intravenous treatment for fluid overload in the previous 24 hours; AND</p> <p>Patient must not have a systolic blood pressure less than 100 mmHg; AND</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated. or</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated. or</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.</p>	
C13569	P13569	CN13569	Sildenafil Tadalafil	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 3 - changing to this drug in combination therapy (dual or triple therapy)</p> <p>The treatment must form part of dual combination therapy consisting of:</p> <p>(i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of dual combination therapy consisting of:</p> <p>(i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of triple combination therapy consisting of:</p> <p>(i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; AND</p>	Compliance with Authority Required procedures

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C13570	P13570	CN13570	Sildenafil Tadalafil	<p>Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; AND</p> <p>Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
C13571	P13571	CN13571	Bosentan	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p>	Compliance with Authority Required procedures

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				<p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	
C13572	P13572	CN13572	Sildenafil Tadalafil	<p>Pulmonary arterial hypertension (PAH)</p> <p>Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
C13573	P13573	CN13573	Sildenafil Tadalafil	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies:</p> <p>(i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND</p> <p>The treatment must form part of dual combination therapy consisting of:</p> <p>(i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	
C13575	P13575	CN13575	Ambrisentan Macitentan	<p>Pulmonary arterial hypertension (PAH) Continuing treatment</p> <p>Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p>	Compliance with Authority Required procedures
C13576	P13576	CN13576	Ambrisentan Macitentan	<p>Pulmonary arterial hypertension (PAH) Initial 2 (change)</p> <p>Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND</p> <p>Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent; AND</p> <p>The treatment must be the sole PBS-subsidised PAH agent for this condition; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures

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C13577	P13577	CN13577	Epoprostenol Iloprost	<p>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.</p> <p>PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.</p> <p>Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p> <p>Pulmonary arterial hypertension (PAH) Continuing treatment Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13580	P13580	CN13580	Ambrisentan Bosentan Macitentan	<p>A maximum of 5 repeats may be requested.</p> <p>Pulmonary arterial hypertension (PAH)</p> <p>Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy consisting of one endothelin receptor antagonist with one prostanoid, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; or</p> <p>Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND</p> <p>The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; or</p> <p>The condition must have, at the time non-PBS combination therapy was initiated, been both:</p> <p>(i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p>	Compliance with Authority Required procedures

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				<p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				management of PAH; document that this has occurred in the patient's medical records. (4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.	
C13582	P13582	CN13582	Ambrisentan Bosentan Macitentan	Pulmonary arterial hypertension (PAH) Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; or The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.	Compliance with Authority Required procedures
C13584	P13584	CN13584	Infliximab	Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND	Compliance with Written Authority Required procedures

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				<p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C13586	P13586	CN13586	Infliximab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must not receive more than 22 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C13587	P13587	CN13587	Infliximab	<p>Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless</p>	

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C13593	P13593	CN13593	Etanercept	<p>the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	

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C13598	P13598	CN13598	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C13599	P13599	CN13599	Adalimumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; or</p> <p>Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age.</p> <p>Active joints are defined as</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measurements must be no more than 4 weeks old at the time of this application. The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C13602	P13602	CN13602	Adalimumab	<p>Severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];</p> <p>Patient must be at least 18 years of age;</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; or</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; or</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy. or</p> <p>Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. or</p> <p>Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.</p> <p>The authority application must be made in writing and must include</p> <p>(1) two completed authority prescription forms; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following</p> <p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>Evidence of intestinal inflammation includes</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.</p> <p>All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	

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				<p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C13609	P13609	CN13609	Adalimumab	<p>Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; or Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; or Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; or Patient must be assessed clinically as being in a high faecal output state; or</p>	<p>Compliance with Written Authority Required procedures</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (1) two completed authority prescription forms; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Evidence of intestinal inflammation includes</p> <ul style="list-style-type: none"> (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. <p>Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p>	

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C13612	P13612	CN13612	Adalimumab	<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13616	P13616	CN13616	Pegcetacoplan	<p>medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>Paroxysmal nocturnal haemoglobinuria (PNH) First continuing treatment Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND The treatment must not be in combination with a Complement 5 (C5) inhibitor; AND Must be treated by a haematologist; or Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L)</p>	Compliance with Authority Required procedures

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				(iv) Reticulocytes (x10 ⁹ /L) (v) Neutrophils (x10 ⁹ /L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH ULN ratio (in figures, rounded to one decimal place)	
C13621	P13621	CN13621	Vericiguat	<p>Chronic heart failure</p> <p>Grandfather treatment</p> <p>Must be treated by a cardiologist; or</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this medicine by a cardiologist; AND</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022; AND</p> <p>Patient must have been symptomatic with NYHA classes II, III or IV prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have had a documented left ventricular ejection fraction (LVEF) of less than 45% prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must have been, at the time of initiating non-PBS-subsidised treatment with this drug, stabilised following a decompensation event that required at least one of:</p> <p>(i) hospitalisation in the 6 months prior to initiating non-PBS-subsidised drug for this PBS indication, (ii) intravenous diuretic therapy in the three months prior to initiating non-PBS-subsidised drug for this PBS indication; AND</p> <p>Patient must not have had clinical signs of fluid overload at the time of initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have received intravenous treatment in the 24 hours prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have a systolic blood pressure less than 100 mmHg; AND</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated. or</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated. or</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated.</p>	
C13624	P13624	CN13624	Leuprorelin	<p>Central precocious puberty Initial treatment Must be treated by a paediatric endocrinologist; or Must be treated by an endocrinologist specialising in paediatrics; Patient must be of an age that is prior to their 10th birthday if female; or Patient must be of an age that is prior to their 11th birthday if male; Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8th birthday if female. or Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if male.</p>	
C13625	P13625	CN13625	Natalizumab	<p>Clinically definite relapsing-remitting multiple sclerosis Must be treated by a neurologist; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord. or Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13625</p>

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				<p>The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.</p> <p>Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.</p> <p>For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.</p>	
C13629	P13629	CN13629	Sildenafil Tadalafil	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient</p> <p>Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. 	

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C13631	P13631	CN13631	Iloprost	<p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class III drug and toxins induced PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. 	

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C13632	P13632	CN13632	Bosentan	<p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>A maximum of 5 repeats may be requested.</p> <p>Pulmonary arterial hypertension (PAH) Initial 1 (new patients) Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent; AND Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH; AND The treatment must be the sole PBS-subsidised PAH agent for this condition; AND Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH. A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <ul style="list-style-type: none"> - RHC composite assessment; and - ECHO composite assessment; and - 6 Minute Walk Test (6MWT) <p>Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; 	

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				<p>- RHC composite assessment only.</p> <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none">- ECHO composite assessment plus 6MWT;- ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <ul style="list-style-type: none">(i) for why fewer than 3 tests are able to be performed on clinical grounds;(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.</p> <p>(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>The test results must not be more than 6 months old at the time of application.</p> <p>If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.</p> <p>Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.</p> <p>If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13634	P13634	CN13634	Epoprostenol Iloprost	<p>Pulmonary arterial hypertension (PAH)</p> <p>Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application</p> <p>Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH; AND</p> <p>Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy; AND</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; or</p> <p>The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; or</p> <p>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p>	Compliance with Authority Required procedures
C13639	P13639	CN13639	Infliximab	<p>Severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; or</p> <p>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have evidence of intestinal inflammation; or</p> <p>Patient must be assessed clinically as being in a high faecal output state; or</p> <p>Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Applications for authorisation must be made in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and</p> <p>(iii) the date of the most recent clinical assessment.</p> <p>Evidence of intestinal inflammation includes</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	

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C13640	P13640	CN13640	Infliximab	<p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 22 weeks of treatment under this restriction; Patient must be at least 18 years of age. An adequate response to treatment is defined as an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	

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C13641	P13641	CN13641	Infliximab	<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have an externally draining enterocutaneous or rectovaginal fistula.</p> <p>Applications for authorisation must be made in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition.</p> <p>The most recent fistula assessment must be no more than 1 month old at the time of application.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13646	P13646	CN13646	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment</p>	Compliance with Written Authority Required procedures

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				<p>with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following <ul style="list-style-type: none"> (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C13647	P13647	CN13647	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <ul style="list-style-type: none"> (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. The most recent PASI assessment must be no more than 1 month old at the time of application. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C13650	P13650	CN13650	Adalimumab	<p>Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or</p>	Compliance with Written Authority Required procedures

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				<p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND</p> <p>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or</p> <p>Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and</p> <p>either</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C13655	P13655	CN13655	Pegcetacoplan	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment (new patient)</p> <p>Patient must not have received prior treatment with this drug for this condition; AND</p> <p>Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months; AND</p> <p>Patient must have experienced an inadequate response to a complement 5 (C5) inhibitor demonstrated by a haemoglobin level of less than 105 g/L; or</p> <p>Patient must be intolerant to C5 inhibitors as determined by the treating physician; AND</p> <p>Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred; AND</p> <p>The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy; AND</p>	Compliance with Authority Required procedures

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C13658	P13658	CN13658	Pegcetacoplan	<p>Must be treated by a haematologist; or Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH ULN ratio (in figures, rounded to one decimal place)</p> <p>Paroxysmal nocturnal haemoglobinuria (PNH) Grandfathered treatment (transition from non-PBS-subsidised treatment after the initial 4 weeks of therapy) Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022; AND Patient must have a documented PNH granulocyte clone size equal to or greater than 10% within the 3 months prior to initiating non-PBS-subsidised treatment with this drug; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have experienced an inadequate response to a complement 5 (C5) inhibitor demonstrated by a haemoglobin level of less than 105 g/L prior to initiating non-PBS-subsidised treatment with this drug; or</p> <p>Patient must be intolerant to C5 inhibitors as determined by the treating physician prior to initiating non-PBS-subsidised treatment with this drug; AND</p> <p>Patient must have been receiving treatment with at least one C5 inhibitor for at least 3 months prior to initiating non-PBS-subsidised treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred; AND</p> <p>The treatment must not be in combination with a Complement 5 (C5) inhibitor; AND</p> <p>Patient must have had at least the initial 4 weeks of pegcetacoplan treatment; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; or</p> <p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>Must be treated by a haematologist; or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(v) Neutrophils (x10 ⁹ /L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH ULN ratio (in figures, rounded to one decimal place)	
C13660	P13660	CN13660	Eculizumab	Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather 2 (transition from LSDP-funded eculizumab) Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND Patient must have experienced clinical improvement as a result of treatment with this drug; or Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; or Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; or Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; or Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; or Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13661	P13661	CN13661	Eculizumab	<p>of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; or</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; or</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	<p>Compliance with Authority Required procedures</p>

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				<p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria; AND Patient must have experienced clinical improvement as a result of treatment with this drug; or Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND Must be treated by a haematologist. or Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13671	P13671	CN13671	Sildenafil Tadalafil	<p>Pulmonary arterial hypertension (PAH) Transitioning from non-PBS to PBS-subsidised supply of combination therapy (dual or triple therapy, excluding selexipag) - Grandfather arrangements where each drug has not been a PBS benefit Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised dual therapy consisting of one endothelin receptor antagonist with one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; or Patient must have been receiving, prior to 1 December 2022, non-PBS-subsidised triple therapy consisting of one endothelin receptor antagonist, one prostanoid, one phosphodiesterase-5 inhibitor, where each drug was not a PBS benefit; this authority application is to continue such combination therapy; AND The condition must have, prior to the time non-PBS combination therapy was initiated, progressed to at least Class III PAH despite treatment with at least one drug from the drug classes mentioned above; or The condition must have, at the time non-PBS combination therapy was initiated, been both:</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above; AND</p> <p>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition</p> <p>(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or</p> <p>(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.</p> <p>(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted</p> <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <p>(i) for why fewer than 3 tests are able to be performed on clinical grounds;</p> <p>(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.</p> <p>(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p> <p>- RHC composite assessment; and</p> <p>- ECHO composite assessment; and</p>	

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				<p>- 6 Minute Walk Test (6MWT) Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - RHC plus ECHO composite assessments; - RHC composite assessment plus 6MWT; - RHC composite assessment only. <p>In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is</p> <ul style="list-style-type: none"> - ECHO composite assessment plus 6MWT; - ECHO composite assessment only. <p>(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s</p> <ul style="list-style-type: none"> (i) for why fewer than 3 tests are able to be performed on clinical grounds; (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records. <p>(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.</p>	
C13681	P13681	CN13681	Adalimumab	<p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>and one of which must be:</p> <p>(i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs:</p> <p>(i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:</p> <p>(i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or</p> <p>Patient must have a contraindication/severe intolerance to each of:</p> <p>(i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.</p>	

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				<p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measurements must be no more than 4 weeks old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C13684	P13684	CN13684	Eculizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)</p> <p>Patient must be planning pregnancy; or</p> <p>Patient must be pregnant; AND</p> <p>Patient must have received PBS-subsidised treatment with ravulizumab for this condition; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.</p>	Compliance with Authority Required procedures
C13691	P13691	CN13691	Infliximab	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>	Compliance with Authority Required procedures

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				<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or Must be treated by a paediatrician; or Must be treated by a specialist paediatric gastroenterologist; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; AND The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; Patient must be aged 6 to 17 years inclusive. Application for authorisation must be made in writing and must include (a) a completed authority prescription form; and (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	
C13692	P13692	CN13692	Infliximab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following <ul style="list-style-type: none"> (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C13694	P13694	CN13694	Adalimumab	<p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <ol style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of</p>	

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				<p>PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C13702	P13702	CN13702	Infliximab	<p>Moderate to severe Crohn disease</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or</p> <p>Must be treated by a paediatrician; or</p> <p>Must be treated by a specialist paediatric gastroenterologist; AND</p> <p>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND</p> <p>Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:</p> <p>(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; or</p> <p>Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND</p> <p>Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment; AND</p> <p>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Application for authorisation must be made in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following</p> <p>(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and</p> <p>(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.</p> <p>The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p>	

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C13710	P13710	CN13710	Pegcetacoplan	<p>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Return from PBS-subsidised eculizumab post pregnancy or from PBS-subsidised Complement 5 (C5) inhibitor for reasons other than post pregnancy</p> <p>Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 3 (switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)' criteria; or</p> <p>Patient must have received prior PBS-subsidised treatment with at least one C5 inhibitor and returning to pegcetacoplan treatment for reasons other than post pregnancy; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; or</p> <p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy; AND</p> <p>Must be treated by a haematologist; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH ULN ratio (in figures, rounded to one decimal place) For the purposes of family planning, patient may qualify under this treatment phase more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, patient may qualify under this treatment phase once only in any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with pegcetacoplan is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of pegcetacoplan.</p>	
C13716	P13716	CN13716	Lorlatinib	<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment</p>	<p>Compliance with Authority Required procedures</p>

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				<p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND</p> <p>The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND</p> <p>Patient must have a WHO performance status of 2 or less;</p> <p>Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.</p>	
C13718	P13718	CN13718	Natalizumab	<p>Clinically definite relapsing-remitting multiple sclerosis</p> <p>Must be treated by a neurologist; AND</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must be ambulatory (without assistance or support); AND</p> <p>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND</p> <p>The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord. or</p> <p>Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.</p> <p>The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.</p> <p>Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.</p> <p>For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13718
C13719	P13719	CN13719	Infliximab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	

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				<p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following <ul style="list-style-type: none"> (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C13726	P13726	CN13726	Pembrolizumab	<p>Relapsed or Refractory Hodgkin lymphoma</p> <p>Initial treatment</p> <p>Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; or</p> <p>Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition;</p> <p>AND</p> <p>Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13726

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13727	P13727	CN13727	Pembrolizumab	<p>Relapsed or refractory primary mediastinal B-cell lymphoma</p> <p>Initial treatment</p> <p>The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of:</p> <p>(i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan; AND</p> <p>Patient must have been treated with rituximab-based chemotherapy for this condition; AND</p> <p>Patient must be experiencing relapsed/refractory disease; AND</p> <p>Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; or</p> <p>Patient must have undergone an autologous stem cell transplant (ASCT); or</p> <p>Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy; AND</p> <p>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13727
C13728	P13728	CN13728	Pembrolizumab	<p>Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer</p> <p>Initial treatment</p> <p>Patient must be untreated for this PBS indication (i.e untreated for each of:</p> <p>(i) unresectable disease, (ii) metastatic disease); AND</p> <p>Patient must not have received prior treatment for colorectal cancer with each of:</p> <p>(i) a programmed cell death-1 (PD-1) inhibitor, (ii) a programmed cell death ligand-1 (PD-L1) inhibitor; AND</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	
C13730	P13730	CN13730	Pembrolizumab	<p>Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.</p>	Compliance with Authority Required procedures
C13731	P13731	CN13731	Pembrolizumab	<p>Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13731
C13732	P13732	CN13732	Pembrolizumab	<p>Relapsed or refractory primary mediastinal B-cell lymphoma</p>	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.</p>	<p>procedures - Streamlined Authority Code 13732</p>
C13735	P13735	CN13735	Pembrolizumab	<p>Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx</p> <p>Initial treatment</p> <p>The condition must be incurable by local therapies in the locally advanced setting; AND</p> <p>Patient must not have had systemic therapy for this condition in the recurrent or metastatic setting prior to initiating PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if previously treated in the locally advanced setting; AND</p> <p>Patient must have had a WHO performance status of 0 or 1; AND</p> <p>The treatment must be either:</p> <p>(i) the sole PBS-subsidised therapy where the condition expresses programmed cell death ligand 1 (PD-L1) with a combined positive score (CPS) greater than or equal to 20 in the tumour sample, (ii) in combination with platinum-based chemotherapy, unless contraindicated or not tolerated; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13735</p>

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C13736	P13736	CN13736	Pembrolizumab	<p>Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13736
C13739	P13739	CN13739	Pembrolizumab	<p>Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer</p> <p>Initial treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The condition must have progressed on or after prior platinum based chemotherapy; or</p> <p>The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; or</p> <p>The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13739

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13741	P13741	CN13741	Pembrolizumab	<p>Relapsed or Refractory Hodgkin lymphoma</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13741</p>
C13743	P13743	CN13743	Pegcetacoplan	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Subsequent continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; or</p> <p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>The treatment must not be in combination with a Complement 5 (C5) inhibitor; AND</p> <p>Must be treated by a haematologist; or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	<p>Compliance with Authority Required procedures</p>

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				At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.	
C13745	P13745	CN13745	Bortezomib	<p>Newly diagnosed systemic light chain amyloidosis</p> <p>Administration on Days 1, 8, 15 and 22 of six treatment cycles (28 days per cycle) in total</p> <p>Patient must be undergoing concurrent treatment with PBS-subsidised daratumumab for this PBS indication.</p>	
C13746	P13746	CN13746	Pomalidomide	<p>Multiple myeloma</p> <p>Initial treatment - dual therapy in combination with dexamethasone</p> <p>The treatment must form part of dual combination therapy limited to:</p> <p>(i) this drug, (ii) dexamethasone; AND</p> <p>Patient must have undergone or be ineligible for a primary stem cell transplant; AND</p> <p>Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information; AND</p> <p>Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and</p> <p>(2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13748	P13748	CN13748	Nirmatrelvir and ritonavir	<p>SARS-CoV-2 infection</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; or</p> <p>Patient must have received a positive rapid antigen test (RAT) result; AND</p> <p>Patient must have at least one sign or symptom attributable to COVID-19; AND</p> <p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13748</p>

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				<p>The treatment must be initiated within 5 days of symptom onset;</p> <p>Patient must be each of:</p> <p>(i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.</p> <p>For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions</p> <ol style="list-style-type: none">1. The patient is in residential aged care2. The patient has disability with multiple comorbidities and/or frailty3. Neurological conditions, including stroke and dementia and demyelinating conditions4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease5. Heart failure, coronary artery disease, cardiomyopathies6. Obesity (BMI greater than 30 kg/m²)7. Diabetes type I or II, requiring medication for glycaemic control8. Renal impairment (eGFR less than 60mL/min)9. Cirrhosis10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above11. Past COVID-19 infection episode resulting in hospitalisation. <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.</p> <p>For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p>	

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C13752	P13752	CN13752	Daratumumab	<p>Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p> <p>Relapsed and/or refractory multiple myeloma</p> <p>Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>The treatment must be in combination with bortezomib and dexamethasone; AND</p> <p>Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised); AND</p> <p>Patient must be undergoing treatment with this drug in one of the following situations:</p> <p>(i) for the first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p>	Compliance with Authority Required procedures

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				<p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Details of the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.</p> <p>Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.</p> <p>A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.</p> <p>A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression,</p>	

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				relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.	
C13753	P13753	CN13753	Leflunomide	<p>Severe active rheumatoid arthritis</p> <p>Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; or</p> <p>Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND</p> <p>The treatment must be initiated by a physician.</p>	
C13755	P13755	CN13755	Pomalidomide	<p>Multiple myeloma</p> <p>Continuing treatment - dual therapy in combination with dexamethasone</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must form part of dual combination therapy limited to:</p> <p>(i) this drug, (ii) dexamethasone.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p>	Compliance with Authority Required procedures

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				(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).	
C13757	P13757	CN13757	Pomalidomide	<p>Multiple myeloma</p> <p>Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>The treatment must form part of triple combination therapy limited to:</p> <p>(i) this drug, (ii) bortezomib, (iii) dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy that is either:</p> <p>(i) lenalidomide monotherapy, (ii) contains lenalidomide; AND</p> <p>Patient must have undergone or be ineligible for a stem cell transplant.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
C13759	P13759	CN13759	Nirmatrelvir and ritonavir	<p>SARS-CoV-2 infection</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; or</p> <p>Patient must have received a positive rapid antigen test (RAT) result; AND</p>	Compliance with Authority Required procedures -

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				<p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>The treatment must be initiated within 5 days of symptom onset; or</p> <p>The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic;</p> <p>Patient must be at least 70 years of age.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	Streamlined Authority Code 13759
C13762	P13762	CN13762	Faricimab	<p>Subfoveal choroidal neovascularisation (CNV)</p> <p>Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND</p> <p>The condition must be due to age-related macular degeneration (AMD); AND</p> <p>The condition must be diagnosed by optical coherence tomography; or</p> <p>The condition must be diagnosed by fluorescein angiography; AND</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2023; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include</p> <p>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.</p> <p>(a) A completed authority prescription form; and</p>	Compliance with Written Authority Required procedures

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C13768	P13768	CN13768	Pomalidomide	<p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(a) A completed authority prescription form; and</p> <p>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>All reports must be documented in the patient's medical records.</p> <p>Multiple myeloma</p> <p>Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must form part of triple combination therapy limited to:</p> <p>(i) this drug, (ii) bortezomib, (iii) dexamethasone; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p>	Compliance with Authority Required procedures

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C13769	P13769	CN13769	Brolocizumab	<p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Subfoveal choroidal neovascularisation (CNV) Initial treatment Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND The condition must be due to age-related macular degeneration (AMD); AND Patient must have persistent macular exudation, as determined clinically and/or by optical coherence tomography or fluorescein angiography, despite at least 6 months of PBS-subsidised treatment with: 1. Aflibercept and/or 2. Ranibizumab and/or 3. Faricimab; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.</p>	Compliance with Written Authority Required procedures

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C13770	P13770	CN13770	Faricimab	<p>Diabetic macular oedema (DMO) Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND Patient must have visual impairment due to diabetic macular oedema; AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND The condition must be diagnosed by optical coherence tomography; or The condition must be diagnosed by fluorescein angiography; AND The treatment must be as monotherapy; or The treatment must be in combination with laser photocoagulation; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2023; AND The treatment must be the sole PBS-subsidised therapy for this condition. The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If the application is submitted through HPOS form upload or mail, it must include (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.</p>	Compliance with Written Authority Required procedures

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C13771	P13771	CN13771	Leflunomide	<p>Severe active psoriatic arthritis</p> <p>Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; or</p> <p>Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND</p> <p>The treatment must be initiated by a physician.</p>	
C13774	P13774	CN13774	Daratumumab	<p>Newly diagnosed systemic light chain amyloidosis</p> <p>Continuing treatment from week 25 onwards (administered once every four weeks)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND</p> <p>Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first:</p> <p>(i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.</p>	Compliance with Authority Required procedures
C13782	P13782	CN13782	Lenalidomide	<p>Relapsed and/or refractory multiple myeloma</p> <p>Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone</p> <p>Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS; AND</p> <p>Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.</p>	Compliance with Authority Required procedures
C13785	P13785	CN13785	Lenalidomide	<p>Multiple myeloma</p> <p>Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle</p> <p>The condition must be newly diagnosed; AND</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>The treatment must form part of triple combination therapy limited to:</p> <p>(i) this drug, (ii) bortezomib, (iii) dexamethasone; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must not have been treated with lenalidomide or bortezomib for this condition; AND</p> <p>The treatment must not exceed a total of 4 cycles under this restriction.</p> <p>The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and</p> <p>(2) nomination of which disease activity parameters will be used to assess response.</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13786	P13786	CN13786	Lenalidomide	<p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <ul style="list-style-type: none"> (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Multiple myeloma</p> <p>Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle</p> <p>The condition must be newly diagnosed; AND</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>The treatment must form part of triple combination therapy limited to:</p> <ul style="list-style-type: none"> (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND <p>Patient must not have been treated with lenalidomide or bortezomib for this condition; AND</p> <p>The treatment must not exceed a total of 4 cycles under this restriction.</p> <p>The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <ul style="list-style-type: none"> (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and (2) nomination of which disease activity parameters will be used to assess response. <ul style="list-style-type: none"> (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or 	Compliance with Written Authority Required procedures

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				<p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine - the percentage of plasma cells; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13787	P13787	CN13787	Lenalidomide	<p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Multiple myeloma</p> <p>Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must form part of dual combination therapy limited to:</p> <p>(i) this drug, (ii) dexamethasone.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures

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C13791	P13791	CN13791	Lenalidomide	<p>Multiple myeloma</p> <p>Initial treatment with lenalidomide monotherapy in newly diagnosed disease</p> <p>The treatment must be as monotherapy; AND</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma; AND</p> <p>Patient must not have progressive disease following autologous stem cell transplant (ASCT).</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and</p> <p>(2) the date the autologous stem cell transplant was performed; and</p> <p>(3) nomination of which disease activity parameters will be used to assess progression.</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine - the percentage of plasma cells; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13801	P13801	CN13801	Lenalidomide	<p>Myelodysplastic syndrome Continuing treatment Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome; AND Patient must have achieved and maintained transfusion independence; or at least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide; AND Patient must not have progressive disease; AND The condition must not have progressed to acute myeloid leukaemia. The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or</p>	Compliance with Authority Required procedures

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C13803	P13803	CN13803	Lenalidomide	<p>mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.</p> <p>The following evidence of response must be provided at each application</p> <ul style="list-style-type: none"> (i) a haemoglobin level taken within the last 4 weeks; and (ii) the date of the last transfusion; and (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; <p>All reports must be documented in the patient's medical records.</p> <p>For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Multiple myeloma</p> <p>Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>The treatment must be as monotherapy; or</p> <p>The treatment must form part of dual combination therapy limited to:</p> <ul style="list-style-type: none"> (i) this drug, (ii) dexamethasone; AND <p>Patient must have progressive disease after at least one prior therapy; AND</p> <p>Patient must have undergone or be ineligible for a primary stem cell transplant.</p> <p>Progressive disease is defined as at least 1 of the following</p> <ul style="list-style-type: none"> (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or 	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and</p> <p>(2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and</p> <p>(3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and</p> <p>(4) details of the basis of the diagnosis of progressive disease or failure to respond; and</p> <p>(5) nomination of which disease activity parameters will be used to assess response.</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c,</p>	

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				<p>d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine - the percentage of plasma cells; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13804	P13804	CN13804	Lenalidomide	<p>Multiple myeloma</p> <p>Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be as monotherapy. Progressive disease is defined as at least 1 of the following (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
C13805	P13805	CN13805	Lenalidomide	<p>Multiple myeloma Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma; AND The treatment must be as monotherapy. or The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.</p>	Compliance with Authority Required procedures
C13810	P13810	CN13810	Lenalidomide	<p>Myelodysplastic syndrome Initial treatment The treatment must be limited to a maximum duration of 16 weeks; AND Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS); AND</p>	Compliance with Authority Required procedures

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				<p>Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND</p> <p>Patient must be red blood cell transfusion dependent.</p> <p>Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.</p> <p>Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations</p> <ol style="list-style-type: none"> 1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR 2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR 5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR 6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR 7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias. <p>Classification of a patient as red blood cell transfusion dependent requires that</p> <ol style="list-style-type: none"> (i) the patient has been transfused within the last 8 weeks; and (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment. <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <ol style="list-style-type: none"> (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and 	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) details (date, unique identifying number/code or provider number) of the full blood examination report; and</p> <p>(c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and</p> <p>(d) details of transfusion requirements including (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application.</p> <p>All the reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS upload or mail, it must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
C13811	P13811	CN13811	Lenalidomide	<p>Multiple myeloma</p> <p>Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)</p> <p>Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND</p> <p>The treatment must form part of triple combination therapy limited to:</p> <p>(i) this drug, (ii) bortezomib, (iii) dexamethasone; AND</p> <p>The treatment must not exceed a total of 4 cycles under this restriction.</p>	Compliance with Authority Required procedures
C13812	P13812	CN13812	Lenalidomide	<p>Multiple myeloma</p> <p>Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation</p> <p>The condition must be newly diagnosed; AND</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must be ineligible for a primary stem cell transplantation; AND</p> <p>The treatment must form part of dual combination therapy limited to:</p> <p>(i) this drug, (ii) dexamethasone.</p>	Compliance with Written Authority Required procedures

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				<p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <ul style="list-style-type: none"> (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and (2) confirmation of ineligibility for prior stem cell transplant; and (3) nomination of which disease activity parameters will be used to assess response. <ul style="list-style-type: none"> (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine - the percentage of plasma cells; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. <p>To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided</p> <ul style="list-style-type: none"> (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine - the percentage of plasma cells; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be</p>	

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C13813	P13813	CN13813	Lenalidomide	<p>stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Authority Required procedures
C13819	P13819	CN13819	Romosozumab	<p>Severe established osteoporosis</p> <p>Initial treatment</p> <p>Patient must be at very high risk of fracture; AND</p> <p>Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND</p> <p>Patient must have had 2 or more fractures due to minimal trauma; AND</p> <p>Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The treatment must not exceed a lifetime maximum of 12 months therapy; AND</p> <p>Patient must not have received treatment with PBS-subsidised teriparatide; or</p> <p>Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy; AND</p> <p>Must be treated by a consultant physician.</p>	Compliance with Authority Required procedures

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				<p>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.</p> <p>If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.</p> <p>If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.</p> <p>Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum. Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.</p>	
C13820	P13820	CN13820	Romosozumab	<p>Severe established osteoporosis</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a lifetime maximum of 12 months therapy; AND</p> <p>Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner.</p>	Compliance with Authority Required procedures
C13821	P13821	CN13821	Nirmatrelvir and ritonavir	<p>SARS-CoV-2 infection</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; or</p> <p>Patient must have received a positive rapid antigen test (RAT) result; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13821

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				<p>Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation; AND The treatment must be initiated within 5 days of symptom onset; Patient must be at least 18 years of age. For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with</p> <ol style="list-style-type: none"> 1. Any primary or acquired immunodeficiency including 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. <ol style="list-style-type: none"> a. Haematologic neoplasms leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, b. Post-transplant solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; <p>OR</p> <ol style="list-style-type: none"> 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 	

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				<p>4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR</p> <p>5. People with disability with multiple comorbidities and/or frailty.</p> <p>a. Chemotherapy or whole body radiotherapy,</p> <p>b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,</p> <p>c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),</p> <p>d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR</p> <p>3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR</p> <p>4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR</p> <p>5. People with disability with multiple comorbidities and/or frailty.</p> <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records</p> <p>For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	
C13839	P13839	CN13839	Nivolumab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Maintenance treatment</p> <p>Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND</p> <p>The treatment must be as monotherapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this PBS indication.</p> <p>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13839
C13845	P13845	CN13845	Eculizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>First Continuing Treatment</p> <p>Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Authority Required procedures

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				<p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <ul style="list-style-type: none"> (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH ULN ratio (in figures, rounded to one decimal place) 	
C13852	P13852	CN13852	Nivolumab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for combination induction therapy</p> <p>Patient must have received non-PBS-subsidised treatment with nivolumab in combination with ipilimumab for this PBS indication prior to 1 March 2023; AND</p> <p>Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to commencing non-PBS-subsidised treatment; AND</p> <p>The condition must not be ocular or uveal melanoma; AND</p> <p>The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.</p> <p>Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.</p> <p>Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13852
C13857	P13857	CN13857	Eculizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)</p> <p>Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have received insufficient quantity to complete the induction treatment phase; AND</p> <p>Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab; AND</p> <p>Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab; AND</p> <p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; or</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; or</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; or</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; or</p> <p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; or</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with eculizumab; or</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p>	

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				<p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH ULN ratio (in figures, rounded to one decimal place)</p>	
C13863	P13863	CN13863	Nivolumab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for maintenance treatment</p> <p>Patient must have previously received of up to maximum 4 doses of PBS-subsidised ipilimumab combined therapy with non-PBS-subsidised nivolumab as induction for this condition prior to 1 March 2023; AND</p> <p>The treatment must be as monotherapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this PBS indication.</p> <p>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13863</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13864	P13864	CN13864	Mepolizumab	<p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p> <p>Chronic rhinosinusitis with nasal polyps (CRSwNP) Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP; AND Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are described below; Patient must be at least 18 years of age. Criteria for Grandfathered patients are that (a) the diagnosis of CRSwNP was confirmed by at least one of (i) nasal endoscopy, (ii) computed tomography (CT) scan; or from at least two physicians of the above mentioned prescriber types (b) the patient has undergone surgery for the removal of nasal polyps; or the patient has the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery (c) the patient had, despite optimised nasal polyp therapy, at least two of (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10) (d) the treatment was/is not used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma (e) the patient had failed to achieve adequate control with optimised nasal polyp therapy which has been documented (f) the patient had a blood eosinophil count greater than or equal to 300 cells per microlitre in the 12 months preceding treatment.</p>	<p>Compliance with Written Authority Required procedures</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Optimised nasal polyp therapy includes</p> <p>(a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated</p> <p>(b) if required, nasal irrigation with saline</p> <p>Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form,</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),</p> <p>(c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,</p> <p>(d) details (date and treatment) of nasal polyp surgery; or</p> <p>(e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,</p> <p>(f) the eosinophil count and date,</p> <p>(g) two of the following, measured within the 12 months prior to non-PBS-subsidised treatment (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.</p>	
C13865	P13865	CN13865	Mepolizumab	<p>Chronic rhinosinusitis with nasal polyps (CRSwNP)</p> <p>Continuing treatment</p> <p>Must be treated by a medical practitioner who is either a:</p> <p>(i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of:</p> <p>(i) an improvement in bilateral endoscopic nasal polyp score of at least 1.0 compared to the baseline level provided with the initial authority application, (ii) an</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13866	P13866	CN13866	Ruxolitinib	<p>improvement in nasal obstruction visual analogue scale (VAS) score of at least 3.0 compared to the baseline level provided with the initial authority application, (iii) an improvement in overall symptom VAS score of at least 2.5 compared to the baseline level provided with the initial authority application; Patient must be at least 18 years of age.</p> <p>Moderate to severe chronic graft versus host disease (cGVHD) Grandfather treatment (transition from non-PBS-subsidised treatment) Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND Patient must have received systemic steroid treatment prior to initiation of this drug for this condition; AND Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response; AND Must be treated by a haematologist; or Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation. Steroid-refractory disease is defined as (a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or (b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent). Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13866</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.</p> <p>Details of prior steroid use should be documented in the patient's medical records.</p> <p>Response is defined as attaining a complete or partial response as defined by the <i>National Institutes of Health</i> (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.</p> <p>(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.</p> <p>(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.</p> <p>The assessment of response must be documented in the patient's medical records.</p> <p>Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	
C13867	P13867	CN13867	Ruxolitinib	<p>Moderate to severe chronic graft versus host disease (cGVHD)</p> <p>Continuing treatment</p> <p>Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a:</p> <p>(i) partial response, (ii) complete response; AND</p> <p>The treatment must be the sole PBS-subsidised treatment for this condition with the exception of:</p> <p>(i) corticosteroids, (ii) calcineurin inhibitors; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13867</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.</p> <p>Response is defined as attaining a complete or partial response as defined by the <i>National Institutes of Health</i> (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.</p> <p>(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.</p> <p>(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.</p> <p>The assessment of response must be documented in the patient's medical records.</p> <p>Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	
C13868	P13868	CN13868	Sapropterin	<p>Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)</p> <p>Initial treatment - responsiveness testing</p> <p>The treatment must be for the purpose of ascertaining the patient's response to treatment over a period of 7 days, with the intent to then use the drug to control phenylalanine levels under the treatment phase:</p> <p>First continuing treatment, Indication: Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU); AND</p> <p>Patient must have a baseline blood phenylalanine level above 250 micromol/L prior to commencing treatment with this drug despite best efforts to rely on dietary modifications to control phenylalanine levels; AND</p> <p>Must be treated by a metabolic physician; AND</p> <p>Patient must be undergoing treatment with this drug for the first time; AND</p> <p>Patient must not be undergoing treatment with this drug under this Treatment phase, more than once per lifetime following completion of this authority application; AND</p>	Compliance with Authority Required procedures

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C13876	P13876	CN13876	Ruxolitinib	<p>Patient must not be undergoing simultaneous treatment with this drug under another PBS-listing (apply under either listing type, but not both simultaneously); Patient must be one of: (i) planning conception, (ii) pregnant.</p> <p>Grade II to IV acute graft versus host disease (aGVHD) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response; AND Must be treated by a haematologist. or Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib. (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD. (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD. The assessment of response must be documented in the patient's medical records. Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13876</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13877	P13877	CN13877	Ruxolitinib	<p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>Grade II to IV acute graft versus host disease (aGVHD) Grandfather treatment (transition from non-PBS-subsidised treatment) Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND Patient must have received systemic steroid treatment prior to initiation of this drug for this condition; AND Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response; AND Must be treated by a haematologist. or Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. Steroid-refractory disease is defined as (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or (b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD. (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days. Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13877</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13880	P13880	CN13880	Sapropterin	<p>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or</p> <p>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.</p> <p>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.</p> <p>Details of prior steroid use should be documented in the patient's medical records.</p> <p>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.</p> <p>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.</p> <p>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.</p> <p>The assessment of response must be documented in the patient's medical records.</p> <p>Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)</p> <p>First continuing treatment</p> <p>Must be treated by a metabolic physician; or</p> <p>Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND</p> <p>Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing.</p> <p>Blood phenylalanine levels must be based on measurements taken during stable periods of the condition.</p> <p>Dietary phenylalanine intake must be maintained at a constant level.</p>	
C13885	P13885	CN13885	Sapropterin	<p>Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)</p> <p>Initial treatment - responsiveness testing</p> <p>Must be treated by a metabolic physician; AND</p> <p>Patient must be untreated with this drug; or</p> <p>Patient must have completed prior responsiveness testing on only 1 occasion - this occurred when the patient was less than 1 month of age, but this benefit is for a second attempt at responsiveness testing in a patient aged at least 1 month old; AND</p> <p>Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; or</p> <p>Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age; AND</p> <p>The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age. or</p> <p>The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month.</p> <p>Dietary phenylalanine intake must be maintained at a constant level.</p> <p>Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.</p>	Compliance with Authority Required procedures
C13886	P13886	CN13886	Calcitonin salmon	<p>Hypercalcaemia</p> <p>The treatment must be initiated in a hospital; AND</p> <p>The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.</p>	Compliance with Authority Required procedures

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C13887	P13887	CN13887	Methyldopa	Hypertension Patient must be pregnant.	Compliance with Authority Required procedures
C13890	P13890	CN13890	Mepolizumab	<p>Chronic rhinosinusitis with nasal polyps (CRSwNP)</p> <p>Initial treatment</p> <p>Must be treated by a medical practitioner who is either a:</p> <p>(i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP; AND</p> <p>Patient must have a diagnosis of CRSwNP confirmed by at least one of:</p> <p>(i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; or</p> <p>Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types; AND</p> <p>Patient must have undergone surgery for the removal of nasal polyps; or</p> <p>Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery; AND</p> <p>Patient must have, despite optimised nasal polyp therapy, at least two of:</p> <p>(i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10); AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of:</p> <p>(i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma; AND</p> <p>Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months;</p> <p>Patient must be at least 18 years of age.</p> <p>Optimised nasal polyp therapy includes</p> <p>(a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated</p> <p>(b) if required, nasal irrigation with saline</p> <p>Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form,</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),</p> <p>(c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,</p> <p>(d) details (date and treatment) of nasal polyp surgery; or</p> <p>(e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,</p> <p>(f) the eosinophil count and date,</p> <p>(g) two of the following, measured within the past 12 months (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.</p>	
C13891	P13891	CN13891	Ruxolitinib	<p>Grade II to IV acute graft versus host disease (aGVHD)</p> <p>Grandfather treatment (transition from non-PBS-subsidised treatment)</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND</p> <p>Patient must have received systemic steroid treatment prior to initiation of this drug for this condition; AND</p> <p>Patient must be one of the following:</p> <p>(i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13891</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a:</p> <p>(i) partial response (ii) complete response; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or</p> <p>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.</p> <p>Steroid-refractory disease is defined as</p> <p>(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or</p> <p>(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.</p> <p>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or</p> <p>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.</p> <p>Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria</p> <p>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or</p> <p>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.</p> <p>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.</p> <p>Details of prior steroid use should be documented in the patient's medical records.</p> <p>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13892	P13892	CN13892	Ruxolitinib	<p>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.</p> <p>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.</p> <p>The assessment of response must be documented in the patient's medical records. Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>Grade II to IV acute graft versus host disease (aGVHD) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response; AND Must be treated by a haematologist. or Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types. Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.</p> <p>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13892

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13900	P13900	CN13900	Nivolumab	<p>aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.</p> <p>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.</p> <p>The assessment of response must be documented in the patient's medical records. Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>Adjuvant treatment of stage II or III oesophageal cancer or gastro-oesophageal junction cancer</p> <p>The condition must have histological evidence confirming a diagnosis of a least one of:</p> <p>(i) adenocarcinoma, (ii) squamous cell cancer; document this evidence in the patient's medical records; AND</p> <p>The condition must have been treated with neoadjuvant platinum-based chemoradiotherapy; AND</p> <p>The treatment must be for the purposes of adjuvant use following complete surgical resection that occurred within 16 weeks prior to initiating this drug; AND</p> <p>The condition must have evidence, through resected specimen, that residual disease meets the Tumour Nodes Metastases (TNM) staging system (as published by the Union for International Cancer Control) of either:</p> <p>(i) at least ypT1, (ii) at least ypN1; document this evidence in the patient's medical records; AND</p> <p>Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must be undergoing treatment with a dosing regimen as set out in the drug's approved Australian Product Information; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not be undergoing PBS-subsidised treatment with this drug where this prescription extends treatment beyond whichever comes first: (i) 12 months from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease recurrence despite treatment with this drug; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	
C13906	P13906	CN13906	Ruxolitinib	Moderate to severe chronic graft versus host disease (cGVHD) Initial treatment Patient must have received prior systemic steroid treatment for this condition; AND Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors; AND Must be treated by a haematologist; or Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation. The severity of cGVHD is defined by the <i>National Institutes of Health</i> (NIH) criteria (Jagasia et al., 2015) (a) Moderate cGVHD at least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1 (b) Severe cGVHD at least 1 organ with a score of 3, or lung score of 2 or 3 Steroid-refractory disease is defined as (a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or (b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).	Compliance with Authority Required procedures - Streamlined Authority Code 13906

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C13907	P13907	CN13907	Ruxolitinib	<p>Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).</p> <p>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.</p> <p>Details of prior steroid use should be documented in the patient's medical records.</p> <p>A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment.</p> <p>Response is defined as attaining a complete or partial response as defined by the <i>National Institutes of Health</i> (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.</p> <p>(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.</p> <p>(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.</p> <p>The assessment of response must be documented in the patient's medical records.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>Grade II to IV acute graft versus host disease (aGVHD)</p> <p>Initial treatment</p> <p>Patient must have received prior systemic steroid treatment for this condition; AND</p> <p>Patient must be one of the following:</p> <p>(i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or</p> <p>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13907</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).</p> <p>Steroid-refractory disease is defined as</p> <ul style="list-style-type: none"> (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or (b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD. <p>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or</p> <p>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.</p> <p>Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria</p> <ul style="list-style-type: none"> (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days. <p>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.</p> <p>Details of prior steroid use should be documented in the patient's medical records.</p> <p>A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.</p> <p>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.</p> <ul style="list-style-type: none"> (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD. 	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13911	P13911	CN13911	Ruxolitinib	<p>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.</p> <p>The assessment of response must be documented in the patient's medical records.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>Grade II to IV acute graft versus host disease (aGVHD)</p> <p>Initial treatment</p> <p>Patient must have received prior systemic steroid treatment for this condition; AND</p> <p>Patient must be one of the following:</p> <p>(i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by an oncologist with allogeneic bone marrow transplantation experience. or</p> <p>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.</p> <p>The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).</p> <p>Steroid-refractory disease is defined as</p> <p>(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or</p> <p>(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.</p> <p>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or</p> <p>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13911</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria</p> <p>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or</p> <p>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.</p> <p>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.</p> <p>Details of prior steroid use should be documented in the patient's medical records.</p> <p>A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.</p> <p>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.</p> <p>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.</p> <p>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.</p> <p>The assessment of response must be documented in the patient's medical records.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	
C13912	P13912	CN13912	Sapropterin	<p>Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)</p> <p>Subsequent continuing</p> <p>Must be treated by a metabolic physician; or</p> <p>Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND</p>	<p>Compliance with Authority Required procedures</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.	
C13913	P13913	CN13913	Calcitonin salmon	Symptomatic Paget disease of bone The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease.	Compliance with Authority Required procedures
C13920	P13920	CN13920	Abacavir	Human immunodeficiency virus (HIV) infection Patient must be less than 13.00 years of age; Patient must be unable to take a solid dose form of this drug; AND The treatment must be in combination with other antiretroviral agents.	Compliance with Authority Required procedures
C13921	P13921	CN13921	Lenvatinib	Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND The condition must be untreated; AND Patient must have a WHO performance status of 2 or less; AND Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib. or Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 13921
C13922	P13922	CN13922	Methylphenidate	Attention deficit hyperactivity disorder Patient must be aged between the ages of 6 and 18 years inclusive; or Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; or	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; or</p> <p>Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age;</p> <p>Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND</p> <p>Patient must require continuous coverage over 8 hours; AND</p> <p>The treatment must not exceed a maximum daily dose of 80 mg with this drug.</p> <p>A retrospective diagnosis of ADHD for the purposes of administering this restriction is</p> <p>(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and</p> <p>(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above.</p>	
C13923	P13923	CN13923	Asciminib	<p>Chronic Myeloid Leukaemia (CML)</p> <p>Continuing treatment for patients without T315I mutation</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%. or</p> <p>Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.</p> <p>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13923
C13925	P13925	CN13925	Asciminib	<p>Chronic Myeloid Leukaemia (CML)</p> <p>Initial PBS-subsidised treatment for patients with T315I mutation</p> <p>The condition must not be in the blast phase; AND</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report; AND The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority. or Patient must have experienced intolerance, not failure to respond, to at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority. Failure of an adequate trial of a tyrosine kinase inhibitor is defined as</p> <ol style="list-style-type: none"> 1. Lack of response defined as either <ol style="list-style-type: none"> (i) failure to achieve a haematological response after a minimum of 3 months therapy; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or (iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR 4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia. <p>Accelerated phase is defined by the presence of 1 or more of the following</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or</p> <p>2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or</p> <p>3. Peripheral basophils greater than or equal to 20%; or</p> <p>4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or</p> <p>5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or</p> <p>(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and</p> <p>(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and</p> <p>(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy</p>	

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C13927	P13927	CN13927	Ustekinumab	<p>Up to a maximum of 18 months of treatment may be authorised under this initial restriction.</p> <p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must not exceed a single dose to be administered at week 8 under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13929	P13929	CN13929	Vosoritide	<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	Compliance with Authority Required procedures

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				<p>(proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months; AND</p> <p>Must be treated by a medical specialist, experienced in the management of achondroplasia. or</p> <p>Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Appropriate genetic testing constitutes testing for FGFR3 gene mutation.</p> <p>In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.</p> <p>Additional radiographic evidence is not required until patient has begun puberty.</p> <p>In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.</p>	
C13930	P13930	CN13930	Upadacitinib	<p>Moderate to severe ulcerative colitis</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND</p> <p>Patient must be receiving treatment with this drug for this condition at the time of application; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND</p> <p>The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; or</p> <p>Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND</p> <p>Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p>	

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				<p>(i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment;</p> <p>(ii) the date of commencement of this drug.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only.</p> <p>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>	
C13932	P13932	CN13932	Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	<p>Cystic fibrosis</p> <p>Initial treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug;</p> <p>Patient must be aged between 6 and 11 years inclusive.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13936	P13936	CN13936	Memantine	<p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include</p> <ul style="list-style-type: none"> (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. <p>Moderately severe Alzheimer disease</p> <p>Initial</p> <p>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND</p> <p>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.</p> <p>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.</p> <p>Patients who qualify under this criterion are from 1 or more of the following groups</p> <ul style="list-style-type: none"> (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; 	Compliance with Authority Required procedures

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				<p>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;</p> <p>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.</p> <p>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.</p>	
C13938	P13938	CN13938	Donepezil Galantamine Rivastigmine	<p>Mild to moderately severe Alzheimer disease</p> <p>Continuing</p> <p>Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND</p> <p>Patient must demonstrate a clinically meaningful response to the initial treatment; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.</p> <p>Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.</p> <p>Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.</p> <p>Clinically meaningful response to treatment is demonstrated in the following areas</p> <p>Patient's quality of life including but not limited to level of independence and happiness;</p> <p>Patient's cognitive function including but not limited to memory, recognition and interest in environment;</p> <p>Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13938
C13940	P13940	CN13940	Donepezil Galantamine Rivastigmine	<p>Mild to moderately severe Alzheimer disease</p> <p>Initial</p> <p>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.</p> <p>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.</p> <p>Patients who qualify under this criterion are from 1 or more of the following groups</p> <ol style="list-style-type: none"> (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background; (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate; (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test; (4) Intellectual (developmental or acquired) disability, eg Down's syndrome; (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test; (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment. <p>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.</p>	
C13941	P13941	CN13941	Donepezil Galantamine Rivastigmine	<p>Mild to moderately severe Alzheimer disease</p> <p>Initial</p> <p>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND</p> <p>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.</p>	Compliance with Authority Required procedures

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C13944	P13944	CN13944	Daratumumab	<p>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.</p> <p>Newly diagnosed systemic light chain amyloidosis</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January 2023; AND</p> <p>The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND</p> <p>The condition must have been, prior to the first dose of the non-PBS-subsidised supply, untreated with drug therapy, including this drug, irrespective of whether the diagnosis had been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND</p> <p>Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated; AND</p> <p>Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND</p> <p>Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information; AND</p> <p>Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include</p> <p>Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to (i) the name of pathologist/pathology provider, (ii) the site of biopsy</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Determine an appropriate number of repeat prescriptions for this authority application in line with either</p> <p>(i) Where the patient has received less than 10 non-PBS-subsidised doses, prescribe a number of repeat prescriptions up to the balance of 15 doses less the number of non-PBS-subsidised doses; or</p> <p>(ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions.</p>	
C13945	P13945	CN13945	Abiraterone	<p>Castration resistant metastatic carcinoma of the prostate</p> <p>The treatment must be used in combination with a corticosteroid; AND</p> <p>The treatment must not be used in combination with chemotherapy; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of:</p> <p>(i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits; AND</p> <p>Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication). or</p> <p>Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.</p>	Compliance with Authority Required procedures
C13946	P13946	CN13946	Ozanimod	<p>Moderate to severe ulcerative colitis</p> <p>Continuing treatment - balance of supply</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND</p>	Compliance with Authority Required procedures

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				The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	
C13948	P13948	CN13948	Pembrolizumab	<p>Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment</p> <p>Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND</p> <p>The condition must be untreated; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; or</p> <p>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13948
C13949	P13949	CN13949	Pembrolizumab	<p>Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; or</p> <p>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13949

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13950	P13950	CN13950	Asciminib	<p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.</p> <p>Chronic Myeloid Leukaemia (CML)</p> <p>Initial PBS-subsidised treatment for patients without T315I mutation</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The condition must not be in the blast phase; AND</p> <p>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND</p> <p>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or</p> <p>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND</p> <p>Patient must have failed an adequate trial of at least two tyrosine kinase inhibitors.</p> <p>or</p> <p>Patient must have experienced intolerance, not failure to respond, to at least two tyrosine kinase inhibitors. or</p> <p>Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor.</p> <p>Failure of an adequate trial of a tyrosine kinase inhibitor is defined as</p> <p>1. Lack of response defined as either</p> <p>(i) failure to achieve a haematological response after a minimum of 3 months therapy; or</p> <p>(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive (Ph+) cells; or</p> <p>(iii) failure to achieve or maintain a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy; OR</p>	Compliance with Authority Required procedures

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				<p>2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph+ cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR</p> <p>3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor (TKI) therapy; OR</p> <p>4. Development of accelerated phase in a patient previously prescribed a TKI inhibitor for any phase of chronic myeloid leukaemia; OR</p> <p>5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during TKI therapy in patients with accelerated phase chronic myeloid leukaemia.</p> <p>Accelerated phase is defined by the presence of 1 or more of the following</p> <ol style="list-style-type: none"> 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). 	
C13952	P13952	CN13952	Ustekinumab	<p>Moderate to severe ulcerative colitis</p> <p>Continuing treatment - balance of supply</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13955	P13955	CN13955	Ustekinumab	<p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.</p> <p>Moderate to severe ulcerative colitis Initial treatment - initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6; or Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND The treatment must not exceed a single dose to be administered at week 8 under this restriction; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p>	
C13958	P13958	CN13958	Upadacitinib	<p>Moderate to severe ulcerative colitis</p> <p>Continuing treatment - balance of supply</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>The treatment must have been prescribed most recently through the Continuing treatment phase in a quantity which did not seek the full number available in regards to any of:</p> <p>(i) the quantity per dispensing, (ii) repeat prescriptions; AND</p> <p>The treatment must provide no more than the balance of 24 weeks treatment.</p>	
C13959	P13959	CN13959	Upadacitinib	<p>Moderate to severe ulcerative colitis</p> <p>Dose modification</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must be undergoing existing PBS-subsidised treatment with this therapy.</p>	Compliance with Authority Required procedures
C13962	P13962	CN13962	Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	<p>Cystic fibrosis</p> <p>Initial treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug;</p> <p>Patient must be at least 6 years of age.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p>	Compliance with Authority Required procedures

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				<p>The authority application must be in writing and must include</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
C13966	P13966	CN13966	Memantine	<p>Moderately severe Alzheimer disease</p> <p>Continuing</p> <p>Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND</p> <p>Patient must demonstrate a clinically meaningful response to the initial treatment; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.</p> <p>Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.</p> <p>Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.</p> <p>Clinically meaningful response to treatment is demonstrated in the following areas</p> <p>Patient's quality of life including but not limited to level of independence and happiness;</p> <p>Patient's cognitive function including but not limited to memory, recognition and interest in environment;</p> <p>Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13966
C13967	P13967	CN13967	Naltrexone	Alcohol dependence	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption.	procedures - Streamlined Authority Code 13967
C13972	P13972	CN13972	Lenvatinib	<p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib. or</p> <p>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records. or</p> <p>Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.</p> <p>In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13972</p>
C13975	P13975	CN13975	Ustekinumab	<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND</p>	<p>Compliance with Authority Required procedures</p>

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				<p>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p> <p>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p> <p>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND</p> <p>The treatment must not exceed a single dose to be administered at week 0 under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p>	
C13976	P13976	CN13976	Ustekinumab	<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a single dose to be administered at week 0 under this restriction; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C13977	P13977	CN13977	Vosoritide	<p>biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>Achondroplasia Initial treatment</p> <p>Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing; AND</p> <p>Patient must not have evidence of growth plate closure demonstrated by at least one of the following:</p> <ul style="list-style-type: none"> i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months; <p>AND</p> <p>Must be treated by a medical specialist, experienced in the management of achondroplasia. or</p> <p>Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>Appropriate genetic testing constitutes testing for FGFR3 gene mutation.</p>	<p>Compliance with Authority Required procedures</p>

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				<p>In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.</p> <p>Additional radiographic evidence is not required until patient has begun puberty.</p> <p>In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.</p>	
C13980	P13980	CN13980	Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	<p>Cystic fibrosis</p> <p>Continuing treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; Patient must be at least 6 years of age.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	Compliance with Authority Required procedures
C13986	P13986	CN13986	Pembrolizumab	<p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 May 2023; AND</p>	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented; AND The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment, (v) treatment is occurring with a dosing regimen specified in this drug's approved Australian Product Information, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	Streamlined Authority Code 13986
C13988	P13988	CN13988	Ustekinumab	<p>Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p>	Compliance with Authority Required procedures

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				<p>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p> <p>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND</p> <p>The treatment must not exceed a single dose to be administered at week 8 under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p>	
C13990	P13990	CN13990	Upadacitinib	<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p>	
C13991	P13991	CN13991	Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	<p>Cystic fibrosis</p> <p>Continuing treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; Patient must be aged between 6 and 11 years inclusive.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
C13992	P13992	CN13992	Abiraterone and methylprednisolone	<p>Castration resistant metastatic carcinoma of the prostate</p> <p>The treatment must not be used in combination with chemotherapy; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of:</p> <p>(i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits; AND</p> <p>Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication). or</p> <p>Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.</p>	Compliance with Authority Required procedures
C13993	P13993	CN13993	Ozanimod	<p>Moderate to severe ulcerative colitis</p> <p>Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements</p> <p>Must be treated by a gastroenterologist (code 87); or</p>	Compliance with Written Authority Required procedures

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				<p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND</p> <p>Patient must be receiving treatment with this drug for this condition at the time of application; AND</p> <p>The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND</p> <p>The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; or</p> <p>Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND</p> <p>Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes (i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment; (ii) the date of commencement of this drug. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>	
C13995	P13995	CN13995	Ozanimod	<p>Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>	<p>Compliance with Written Authority Required procedures</p>

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND</p> <p>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p> <p>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p> <p>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p>	
C13998	P13998	CN13998	Vosoritide	<p>Achondroplasia</p> <p>Continuing treatment</p> <p>Patient must have received PBS subsidised vosoritide treatment for this condition; AND</p> <p>Patient must not have evidence of growth plate closure demonstrated by at least one of the following:</p> <ul style="list-style-type: none"> i) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 6 months of this application if puberty has commenced; ii) bilateral lower extremity X-rays (proximal tibia, distal femur) taken within 2 years of commencing treatment if puberty has not commenced; iii) an annual growth velocity of greater than 1.5 cm/year as assessed over a period of at least 6 months; AND <p>Must be treated by a medical specialist, experienced in the management of achondroplasia. or</p>	Compliance with Authority Required procedures

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				<p>Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>In patients where puberty has not commenced, radiographic evidence that epiphyses have not closed must be obtained within 2 years of commencing treatment with vosoritide. X-rays and dates (date commenced treatment and date of X-ray) must be documented in the patient's medical records.</p> <p>Additional radiographic evidence is not required until patient has begun puberty.</p> <p>In patients where puberty has commenced, radiographic evidence that epiphyses have not closed must be obtained within 6 months of completing an authority application for vosoritide. X-ray and date taken must be documented in the patient's medical records.</p>	
C13999	P13999	CN13999	Upadacitinib	<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 1 (new patient - untreated with biological medicine)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND</p> <p>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p> <p>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p>	
C14000	P14000	CN14000	Memantine	<p>Moderately severe Alzheimer disease</p> <p>Initial</p> <p>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14; AND</p> <p>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.</p> <p>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.</p>	Compliance with Authority Required procedures
C14001	P14001	CN14001	Nivolumab	<p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Induction treatment</p> <p>The condition must not have previously been treated; AND</p> <p>Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either:</p> <p>(i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14001

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14002	P14002	CN14002	Ozanimod	<p>Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p> <p>Moderate to severe ulcerative colitis</p> <p>Continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	Compliance with Authority Required procedures

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C14003	P14003	CN14003	Ozanimod	<p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p>	
C14004	P14004	CN14004	Ozanimod	<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p>	
C14005	P14005	CN14005	Ozanimod	<p>Moderate to severe ulcerative colitis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	
C14007	P14007	CN14007	Lenvatinib	<p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements</p> <p>Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 May 2023; AND</p> <p>Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either:</p> <p>(i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented; AND</p> <p>The treatment must be occurring in a patient where each of the following is true:</p> <p>(i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14007
C14008	P14008	CN14008	Asciminib	<p>Chronic Myeloid Leukaemia (CML)</p> <p>Continuing Treatment for patients with T315I mutation</p> <p>Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%. or</p> <p>Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a 12-month response of either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%.</p> <p>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.</p> <p>The continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or</p> <p>(ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy</p>	
C14009	P14009	CN14009	Ustekinumab	<p>Moderate to severe ulcerative colitis</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND</p> <p>Patient must be receiving treatment with this drug for this condition at the time of application; AND</p> <p>The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND</p> <p>The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; or</p> <p>The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; or</p> <p>Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND</p> <p>Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available; AND</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment;</p> <p>(ii) the date of commencement of this drug.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only.</p> <p>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>	
C14010	P14010	CN14010	Ustekinumab	<p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p> <p>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND</p> <p>The treatment must not exceed a single dose to be administered at week 0 under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p>	

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14011	P14011	CN14011	Upadacitinib	<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>Moderate to severe ulcerative colitis</p> <p>Continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug;</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14014	P14014	CN14014	Upadacitinib	<p>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p>	Compliance with Written Authority Required procedures

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Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14015	P14015	CN14015	Daratumumab	<p>Newly diagnosed systemic light chain amyloidosis</p> <p>Initial treatment from week 0 to week 24</p> <p>The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND</p> <p>The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation; AND</p> <p>Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND</p> <p>Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include</p> <p>Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to (i) the name of pathologist/pathology provider, (ii) the site of biopsy</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Authority Required procedures
C14017	P14017	CN14017	Ozanimod	<p>Moderate to severe ulcerative colitis</p> <p>Dose escalation occurring at initial treatment or re-initiation of treatment</p> <p>Must be treated by a gastroenterologist (code 87). or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14017

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14018	P14018	CN14018	Ustekinumab	<p>Moderate to severe ulcerative colitis</p> <p>Continuing treatment</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14021	P14021	CN14021	Selinexor	<p>Relapsed and/or refractory multiple myeloma</p> <p>Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must be undergoing triple combination therapy limited to:</p> <p>(i) this drug, (ii) bortezomib, (iii) dexamethasone; or</p> <p>Patient must be undergoing dual combination therapy limited to:</p> <p>(i) this drug, (ii) dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy; AND</p> <p>Patient must not have previously received this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Details of the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.</p> <p>Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.</p> <p>Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy</p>	
C14022	P14022	CN14022	Selinexor	<p>Relapsed and/or refractory multiple myeloma</p> <p>Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg, 60 mg or 40 mg per week</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND</p> <p>Patient must have met all initial treatment PBS eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14023	P14023	CN14023	Selinexor	<p>are:</p> <p>(a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Relapsed and/or refractory multiple myeloma</p> <p>Continuing treatment - Dose requirement of 100 mg per week</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing triple combination therapy limited to:</p> <p>(i) this drug, (ii) bortezomib, (iii) dexamethasone; or</p>	Compliance with Authority Required procedures

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C14024	P14024	CN14024	Selinexor	<p>Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
				<p>Relapsed and/or refractory multiple myeloma</p> <p>Initial treatment - Dose requirement of 100 mg per week</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; or</p> <p>Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy; AND</p> <p>Patient must not have previously received this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy</p>	
C14026	P14026	CN14026	Ciclosporin	<p>Chronic severe dry eye disease with keratitis</p> <p>Initial treatment for up to the first 180 days of treatment</p> <p>Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of:</p> <p>(i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber; AND</p> <p>Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation; AND</p> <p>The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute; AND</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14027	P14027	CN14027	Pembrolizumab	<p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; or</p> <p>Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines; AND</p> <p>Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment;</p> <p>Patient must be at least 18 years of age.</p> <p>Prescribing instruction</p> <p>State in the first authority application for this drug, for the purpose of having a baseline measurement to assess response to treatment under the Continuing treatment listing, each of (i) the qualifying corneal fluorescein staining grade (a numerical value no less than 4), (ii) the qualifying ocular surface disease index score (a numerical value no less than 23).</p> <p>Advanced, metastatic or recurrent endometrial carcinoma</p> <p>Initial treatment</p> <p>Patient must have received prior treatment with platinum-based chemotherapy; AND</p> <p>The condition must be untreated with each of:</p> <p>(i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND</p> <p>Patient must be undergoing combination therapy consisting of:</p> <p>(i) pembrolizumab, (ii) lenvatinib; or</p> <p>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14027</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14028	P14028	CN14028	Pembrolizumab	<p>Advanced, metastatic or recurrent endometrial carcinoma</p> <p>Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsided treatment with this drug for this condition prior to 1 June 2023; AND</p> <p>The treatment must be occurring in a patient where each of the following is true:</p> <p>(i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (v) disease progression has not occurred whilst on treatment, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14028</p>
C14031	P14031	CN14031	Selinexor	<p>Relapsed and/or refractory multiple myeloma</p> <p>Continuing treatment - Dose requirement of 160 mg per week</p> <p>Patient must have previously received PBS-subsided treatment with this drug for this condition; AND</p> <p>Patient must be undergoing dual combination therapy limited to:</p> <p>(i) this drug, (ii) dexamethasone; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p>	<p>Compliance with Authority Required procedures</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14032	P14032	CN14032	Ciclosporin	<p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Chronic severe dry eye disease with keratitis</p> <p>Continuing treatment</p> <p>Patient must have received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must have improved to an extent that corneal fluorescein staining, using the same scale used at the time of the first authority application, shows an improvement (reduction) by at least 3 grades from baseline (the grade stated in the first authority application) - the improvement need only be demonstrated by staining once only with the first Continuing treatment authority application; AND</p> <p>The condition must have improved to an extent that the patient's ocular surface disease index score at the time of this authority application, has improved (reduced) by at least 30% compared to the value stated in the first authority application (i.e. baseline); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. or</p> <p>Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines.</p> <p>Prescribing instructions</p> <p>State in the first continuing treatment authority application for this drug</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) an improved corneal fluorescein staining grade (a numerical value that has improved by 3 grades from that provided in the first Initial 1 treatment authority application). (ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application). State in all continuing treatment authority applications (ii) the ocular surface disease index score at the time of this authority application (a numerical value that is at least 30% lower than that stated in the first Initial 1 treatment authority application).	
C14034	P14034	CN14034	Abiraterone and methylprednisolone Apalutamide Darolutamide Enzalutamide	Metastatic castration sensitive carcinoma of the prostate The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); or Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND Patient must be undergoing concurrent androgen deprivation therapy.	Compliance with Authority Required procedures
C14037	P14037	CN14037	Selinexor	Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND Patient must have met all initial treatment PBS eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (a) the condition was confirmed by histological diagnosis, (b) the treatment is/was being used as part of combination therapy limited to this drug in combination with either: (i) dexamethasone, (ii) dexamethasone plus bortezomib, (c) the condition	Compliance with Authority Required procedures

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				<p>progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
C14039	P14039	CN14039	Selinexor	<p>Relapsed and/or refractory multiple myeloma</p> <p>Initial treatment - Dose requirement of 160 mg per week</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must be undergoing dual combination therapy limited to:</p> <p>(i) this drug, (ii) dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy; AND</p> <p>Patient must not have previously received this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy</p>	
C14040	P14040	CN14040	Nicotine	<p>Nicotine dependence</p> <p>The treatment must be as an aid to achieving abstinence from smoking; AND</p> <p>The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation; AND</p> <p>Patient must have indicated they are ready to cease smoking; AND</p> <p>Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period; AND</p> <p>Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.</p> <p>Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.</p>	
C14041	P14041	CN14041	Lenvatinib	<p>Advanced, metastatic or recurrent endometrial carcinoma</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p>	<p>Compliance with Authority Required procedures -</p>

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				<p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib. or</p> <p>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records. or</p> <p>Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.</p>	Streamlined Authority Code 14041
C14042	P14042	CN14042	Lenvatinib	<p>Advanced, metastatic or recurrent endometrial carcinoma Initial treatment</p> <p>Patient must have received prior treatment with platinum-based chemotherapy; AND</p> <p>The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND</p> <p>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib. or</p> <p>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14042
C14043	P14043	CN14043	Lenvatinib	<p>Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND</p> <p>The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14043

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (v) disease progression has not occurred whilst on treatment.	
C14044	P14044	CN14044	Pembrolizumab	<p>Advanced, metastatic or recurrent endometrial carcinoma</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; or</p> <p>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND</p> <p>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14044
C14045	P14045	CN14045	Selinexor	<p>Relapsed and/or refractory multiple myeloma</p> <p>Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; or</p> <p>Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
C14047	P14047	CN14047	Cannabidiol	<p>Seizures of the Lennox-Gastaut syndrome</p> <p>Patient must have a diagnosis of Lennox-Gastaut syndrome confirmed by an electroencephalogram (EEG) that showed a pattern of slow (less than 3.0 hertz) spike-and-wave discharges with generalised paroxysmal fast activity (sleep recording should be obtained where it is possible); AND</p> <p>Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had at least two drop seizures (atonic, tonic or tonic-clonic) per week that are not adequately controlled with at least two other anti-epileptic drugs prior to initiating treatment with this medicine; AND</p> <p>The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs; AND</p> <p>Must be treated by a neurologist if treatment is being initiated. or</p> <p>Must be treated by a neurologist if treatment is being continued or re-initiated. or</p> <p>Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued. or</p> <p>Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.</p> <p>Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness.</p> <p>Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.</p>	
C14054	P14054	CN14054	Avatrombopag	<p>Severe thrombocytopenia</p> <p>Second or Subsequent Continuing treatment</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction; AND</p> <p>Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures
C14061	P14061	CN14061	Adalimumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; or</p>	Compliance with Authority Required procedures

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				<p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14063	P14063	CN14063	Adalimumab	<p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p> <p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Active joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p>	Compliance with Authority Required procedures

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				<p>All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic; and</p> <p>(b) the date of the last continuing prescription.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14064	P14064	CN14064	Adalimumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or</p> <p>Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens:</p> <p>(i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; OR</p> <p>(b) at least 4 active joints from the following list</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p>	

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				<p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14068	P14068	CN14068	Etanercept	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting</p>	

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C14070	P14070	CN14070	Etanercept	<p>in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p> <p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; OR</p> <p>(b) at least 4 active joints from the following list</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks</p>	

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				<p>from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14071	P14071	CN14071	Etanercept	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have either:</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Active joints are defined as</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) the date of the last continuing prescription.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14074	P14074	CN14074	Buprenorphine with naloxone	<p>Opioid dependence</p> <p>The treatment must be within a framework of medical, social and psychological treatment.</p> <p>A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14074
C14075	P14075	CN14075	Buprenorphine	<p>Opioid dependence</p> <p>Must be treated by a health care professional; AND</p> <p>The treatment must be within a framework of medical, social and psychological treatment.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14075

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C14080	P14080	CN14080	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient weighing at least 30 kg)</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or</p> <p>Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; or</p> <p>Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(a) an active joint count of at least 2 active joints; and</p> <p>(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or</p> <p>(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.</p> <p>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p>	

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C14082	P14082	CN14082	Tocilizumab	<p>(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. The following reports must be documented in the patient's medical records where appropriate (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; (b) details of prior treatment including dose and duration of treatment; and (c) the pathology reports detailing CRP and platelet count where appropriate.</p> <p>Severe active juvenile idiopathic arthritis Continuing treatment Must be treated by a rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14082</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14083	P14083	CN14083	Tocilizumab	<p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	Compliance with Authority Required procedures

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				<p>Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have either:</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Active joints are defined as</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) the date of the last continuing prescription.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14084	P14084	CN14084	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Continuing treatment in a patient weighing less than 30 kg</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>An adequate response to treatment is defined as</p> <p>(a) in a patient with polyarticular course disease</p> <p>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14084</p>

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				<p>- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14085	P14085	CN14085	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND</p> <p>Patient must have polyarticular course disease and the condition must have at least one of:</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); or</p> <p>Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre;</p> <p>Patient must be under 18 years of age.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.</p> <p>The following reports must be documented in the patient's medical records where appropriate</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14088	P14088	CN14088	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Continuing treatment in a patient weighing at least 30 kg</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>An adequate response to treatment is defined as</p> <p>(a) in a patient with polyarticular course disease</p> <p>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14088

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.</p> <p>The following reports must be documented in the patient's medical records where appropriate</p> <p>(a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and</p> <p>(b) baseline and current pathology reports detailing platelet count.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14091	P14091	CN14091	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)</p> <p>Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>An adequate response to treatment is defined as</p> <p>(a) in a patient with polyarticular course disease</p> <p>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.</p> <p>The following reports must be documented in the patient's medical records where appropriate</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retriial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p>	

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C14093	P14093	CN14093	Tocilizumab	<p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Systemic juvenile idiopathic arthritis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as (a) in a patient with polyarticular course disease (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50% (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14093

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.</p> <p>At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an</p>	

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				<p>adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14094	P14094	CN14094	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient weighing less than 30 kg)</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or</p> <p>Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; or</p> <p>Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application</p> <p>(a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.</p> <p>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and</p> <p>(b) the details of prior treatment including dose and duration of treatment.</p> <p>The following reports must be documented in the patient's medical records where appropriate</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p>	
C14096	P14096	CN14096	Choriogonadotropin alfa	<p>Infertility indications other than that of Assisted Reproductive Technology</p> <p>Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule; AND</p> <p>Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing; AND</p> <p>Must be treated by an obstetrician/gynaecologist. or</p> <p>Must be treated by a specialist in reproductive endocrinology/infertility. or</p> <p>Must be treated by a urogynaecologist. or</p> <p>Must be treated by an endocrinologist. or</p> <p>Must be treated by a urologist.</p> <p>The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number.</p>	
C14097	P14097	CN14097	Finerenone	<p>Chronic kidney disease with Type 2 diabetes</p> <p>Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of:</p> <p>(i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14097</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug; AND</p> <p>Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 m² or greater, prior to initiating treatment with this drug; AND</p> <p>Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, prior to initiating treatment with this drug; AND</p> <p>Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND</p> <p>Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug; AND</p> <p>The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant; AND</p> <p>Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic; AND</p> <p>Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist.</p>	
C14098	P14098	CN14098	Romiplostim	<p>Severe thrombocytopenia</p> <p>Initial treatment - New patient</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;</p> <p>(a) a platelet count of less than or equal to 20,000 million per L; OR</p>	Compliance with Written Authority Required procedures

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C14099	P14099	CN14099	Romiplostim	<p>(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.</p> <p>The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.</p> <p>Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.</p> <p>Authority approval will not be given for doses higher than 10 micrograms/kg/week</p> <p>The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) details of a platelet count supporting the diagnosis of ITP.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p> <p>Severe thrombocytopenia</p> <p>First Continuing treatment or Re-initiation of interrupted continuing treatment</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have changed treatment from either eltrombopag or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; or</p> <p>Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.</p> <p>The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.</p> <p>Authority approval will not be given for doses higher than 10 micrograms/kg/week</p> <p>The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.</p>	
C14101	P14101	CN14101	Avatrombopag	<p>Severe thrombocytopenia</p> <p>First Continuing treatment or Re-initiation of interrupted continuing treatment</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment or Grandfather treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; or</p> <p>Patient must have changed treatment from either romiplostim or eltrombopag to this drug under the Balance of Supply/Change of Therapy restriction and demonstrated a sustained response; or</p> <p>Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority; AND</p>	Compliance with Authority Required procedures

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C14103	P14103	CN14103	Tocilizumab	<p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.</p> <p>The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.</p> <p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; OR</p> <p>(b) at least 4 active joints from the following list</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14104	P14104	CN14104	Tocilizumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must be under 30kg; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14104

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
C14107	P14107	CN14107	Adalimumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14107</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
C14121	P14121	CN14121	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND</p> <p>Patient must have polyarticular course disease and the condition must have at least one of:</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); or</p> <p>Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre;</p> <p>Patient must be under 18 years of age.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.</p> <p>The following reports must be documented in the patient's medical records where appropriate</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14124	P14124	CN14124	Choriogonadotropin alfa	<p>Assisted Reproductive Technology</p> <p>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule; AND</p> <p>Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14124
C14126	P14126	CN14126	Eltrombopag	<p>Severe thrombocytopenia</p> <p>Initial treatment - New patient</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;</p> <p>(a) a platelet count of less than or equal to 20,000 million per L; OR</p> <p>(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.</p> <p>The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(a) details of a platelet count supporting the diagnosis of ITP. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p>	
C14127	P14127	CN14127	Eltrombopag	<p>Severe thrombocytopenia Balance of supply or change of therapy The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; or Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; or Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; or Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition; AND The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction. Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.</p>	Compliance with Authority Required procedures
C14129	P14129	CN14129	Eltrombopag	<p>Severe thrombocytopenia First Continuing treatment or Re-initiation of interrupted continuing treatment The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p>	Compliance with Authority Required procedures

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				<p>Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; or</p> <p>Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; or</p> <p>Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.</p> <p>The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.</p>	
C14130	P14130	CN14130	Avatrombopag	<p>Severe thrombocytopenia Initial treatment - New patient</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;</p> <p>(a) a platelet count of less than or equal to 20,000 million per L; OR</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.</p> <p>The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include (a) details of a platelet count supporting the diagnosis of ITP.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p> <p>A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.</p>	
C14131	P14131	CN14131	Avatrombopag	<p>Severe thrombocytopenia</p> <p>Balance of supply or change of therapy</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Grandfather treatment restriction; or</p> <p>Patient must be changing therapy from romiplostim or eltrombopag to this drug for this condition; AND</p>	Compliance with Authority Required procedures

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				<p>The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.</p> <p>Patients receiving treatment with romiplostim or eltrombopag may change to avatrombopag under this restriction.</p>	
C14132	P14132	CN14132	Avatrombopag	<p>Severe thrombocytopenia</p> <p>Grandfather treatment</p> <p>The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2023; AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated a sustained platelet response to the non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.</p> <p>The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include</p> <p>(a) details of a platelet count supporting the diagnosis of ITP.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;</p> <p>(a) a platelet count of less than or equal to 20,000 million per L; OR</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14136	P14136	CN14136	Adalimumab	<p>(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.</p> <p>The platelet count must have been no more than 4 weeks old at the time that non-PBS-subsidised treatment with this drug was initiated and must be documented in the patient's medical records.</p> <p>For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.</p> <p>A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the First Continuing treatment or Re-initiation of interrupted continuing treatment criteria.</p> <p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14136</p>

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				<p>active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
C14138	P14138	CN14138	Buprenorphine	<p>Opioid dependence</p> <p>Must be treated by a health care professional; AND</p> <p>The treatment must be within a framework of medical, social and psychological treatment; AND</p> <p>Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14138</p>
C14139	P14139	CN14139	Buprenorphine	<p>Opioid dependence</p> <p>Must be treated by a health care professional; AND</p>	<p>Compliance with Authority Required procedures -</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be within a framework of medical, social and psychological treatment; AND</p> <p>Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition:</p> <p>(i) weekly prolonged release buprenorphine (Bupival Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.</p>	Streamlined Authority Code 14139
C14145	P14145	CN14145	Tocilizumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is</p>	Compliance with Authority Required procedures

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				<p>required for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
C14147	P14147	CN14147	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND</p> <p>Patient must have polyarticular course disease and the condition must have at least one of:</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); or</p> <p>Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre;</p> <p>Patient must be under 18 years of age.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.</p> <p>The following reports must be documented in the patient's medical records where appropriate</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p>	

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C14148	P14148	CN14148	Tocilizumab	<p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Systemic juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age; Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application</p> <ul style="list-style-type: none"> (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN). <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.</p> <p>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p>	

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C14149	P14149	CN14149	Romiplostim	<p>(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and (b) the details of prior treatment including dose and duration of treatment. The following reports must be documented in the patient's medical records where appropriate (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>Severe thrombocytopenia Balance of supply or change of therapy The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition; AND Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; or Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; or Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; or Patient must be changing therapy from eltrombopag or avatrombopag to this drug for this condition; AND The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction. Patients receiving treatment with eltrombopag or avatrombopag may change to romiplostim under this restriction.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14150	P14150	CN14150	Tocilizumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must be 30kg or over; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14150</p>

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C14153	P14153	CN14153	Tocilizumab	<p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p> <p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints. Active joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.</p> <p>Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) the date of the last continuing prescription.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14154	P14154	CN14154	Etanercept	<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14154</p>

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				<p>Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved</p>	

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				<p>in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
C14155	P14155	CN14155	Etanercept	<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14155</p>

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				<p>At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
C14157	P14157	CN14157	Buprenorphine	<p>Opioid dependence</p> <p>The treatment must be within a framework of medical, social and psychological treatment.</p> <p>A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14157
C14162	P14162	CN14162	Tocilizumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or</p> <p>Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens:</p> <ul style="list-style-type: none"> (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; <p>AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <ul style="list-style-type: none"> (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list <ul style="list-style-type: none"> (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to 	

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				<p>active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14164	P14164	CN14164	Tocilizumab	<p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14164</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised. The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	

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C14166	P14166	CN14166	Tocilizumab	<p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p> <p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Patients under 30 kg may receive up to 24 weeks of treatment under this restriction.</p> <p>Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
C14175	P14175	CN14175	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing at least 30 kg)</p> <p>Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>An adequate response to treatment is defined as</p> <p>(a) in a patient with polyarticular course disease</p> <p>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>The following reports must be documented in the patient's medical records where appropriate</p> <p>(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14178	P14178	CN14178	Methadone	<p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Opioid dependence</p> <p>The treatment must be within a framework of medical, social and psychological treatment.</p> <p>A medical practitioner must request a quantity (in millilitres) sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14178</p>
C14179	P14179	CN14179	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.</p> <p>An adequate response to treatment is defined as</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14179</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(a) in a patient with polyarticular course disease</p> <p>(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>(b) in a patient with refractory systemic symptoms</p> <p>(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or</p> <p>(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or</p> <p>(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.</p> <p>The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.</p> <p>At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14180	P14180	CN14180	Fluticasone propionate	<p>Asthma</p> <p>The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14180
C14182	P14182	CN14182	Tocilizumab	<p>Systemic juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg)</p> <p>Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age;</p>	Compliance with Authority Required procedures

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				<p>Must be treated by a rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. An adequate response to treatment is defined as (a) in a patient with polyarticular course disease (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50% (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). (b) in a patient with refractory systemic symptoms (i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or (ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or (iii) a reduction in the dose of corticosteroid by at least 30% from baseline. The assessment of response to treatment must be documented in the patient's medical records. The following reports must be documented in the patient's medical records where appropriate (a) pathology reports detailing C-reactive protein (CRP) level and platelet count. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14188	P14188	CN14188	Trabectedin	<p>drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have been receiving treatment with this drug for this condition prior to 1 August 2023; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated; AND Patient must have received chemotherapy treatment including an anthracycline, prior to initiating non-PBS-subsidised treatment; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14188

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C14189	P14189	CN14189	Eptinezumab	<p>Chronic migraine</p> <p>Initial treatment</p> <p>Must be treated by a neurologist; AND</p> <p>Patient must not be undergoing concurrent treatment with the following PBS benefits:</p> <p>(i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication; AND</p> <p>Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND</p> <p>Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND</p> <p>Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug;</p> <p>Patient must be at least 18 years of age.</p> <p>Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.</p> <p>Patient must have the number of migraine days per month documented in their medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14189
C14195	P14195	CN14195	Tocilizumab	<p>Active giant cell arteritis</p> <p>Initial treatment</p> <p>Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis; AND</p> <p>Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause; AND</p> <p>Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; or</p> <p>Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; or</p> <p>Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis; AND</p> <p>Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; or</p> <p>Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; or</p> <p>Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis; AND</p> <p>The treatment must be in combination with a tapering course of corticosteroids; AND</p> <p>The treatment must not exceed 52 weeks in total including initial and continuing applications;</p> <p>Patient must be aged 50 years or older.</p> <p>Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include</p> <p>(a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging; and</p> <p>(b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14196	P14196	CN14196	Trabectedin	<p>Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND Patient must have received prior chemotherapy treatment including an anthracycline; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14196
C14197	P14197	CN14197	Trabectedin	<p>Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14197
C14202	P14202	CN14202	Mifepristone and misoprostol	<p>Termination of an intra-uterine pregnancy The condition must be an intra-uterine pregnancy of up to 63 days of gestation.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14202
C14217	P14217	CN14217	Upadacitinib	<p>Non-radiographic axial spondyloarthritis Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p>	
C14228	P14228	CN14228	Calcium	<p>Hyperphosphataemia</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The condition must be associated with chronic renal failure.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14228
C14229	P14229	CN14229	Mesalazine	<p>Crohn disease</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	
C14231	P14231	CN14231	Calcitriol	<p>Hypophosphataemic rickets</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14231
C14234	P14234	CN14234	Risedronic acid	<p>Corticosteroid-induced osteoporosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND</p>	

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				<p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p>	
C14235	P14235	CN14235	Risedronic acid	<p>Osteoporosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient;</p> <p>Patient must be aged 70 years or older;</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p>	
C14236	P14236	CN14236	Calcipotriol with betamethasone	<p>Chronic stable plaque type psoriasis vulgaris</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The condition must be inadequately controlled by potent topical corticosteroid monotherapy.</p>	
C14238	P14238	CN14238	<p>Acarbose</p> <p>Allopurinol</p> <p>Amlodipine</p> <p>Amlodipine with atorvastatin</p> <p>Atenolol</p> <p>Atorvastatin</p> <p>Baclofen</p> <p>Candesartan</p>	<p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Carbamazepine		
			Carbimazole		
			Chlortalidone		
			Ciclosporin		
			Clonidine		
			Clopidogrel		
			Clopidogrel with aspirin		
			Cortisone		
			Cyproterone		
			Dexamethasone		
			Enalapril		
			Eprosartan		
			Estradiol		
			Estradiol and estradiol with dydrogesterone		
			Estradiol and estradiol with norethisterone		
			Estradiol with norethisterone		
			Estriol		
			Ethosuximide		
			Everolimus		
			Felodipine		

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			Fenofibrate		
			Fluvastatin		
			Furosemide		
			Gemfibrozil		
			Glibenclamide		
			Gliclazide		
			Glimepiride		
			Glipizide		
			Glyceryl trinitrate		
			Hydrochlorothiazide		
			Hydrochlorothiazide with amiloride		
			Hydrocortisone		
			Indapamide		
			Irbesartan		
			Isosorbide dinitrate		
			Isosorbide mononitrate		
			Labetalol		
			Lercanidipine		
			Lisinopril		
			Medroxyprogesterone		
			Metformin		
			Methenamine		

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Methotrexate		
			Metoprolol		
			Mycophenolic acid		
			Nicorandil		
			Nifedipine		
			Norethisterone		
			Olmesartan		
			Pancreatic extract		
			Penicillamine		
			Perindopril		
			Perindopril with indapamide		
			Phenytoin		
			Pizotifen		
			Potassium chloride		
			Potassium chloride with potassium bicarbonate		
			Pravastatin		
			Prazosin		
			Prednisolone		
			Prednisone		
			Probenecid		
			Propranolol		
			Propylthiouracil		

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			Ramipril		
			Rosuvastatin		
			Simvastatin		
			Sirolimus		
			Sodium bicarbonate		
			Spironolactone		
			Sulfasalazine		
			Sulthiame		
			Tacrolimus		
			Telmisartan		
			Toremifene		
			Trandolapril		
			Valproic acid		
			Valsartan		
			Verapamil		
C14240	P14240	CN14240	Ticagrelor	Acute coronary syndrome (myocardial infarction or unstable angina) The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with aspirin.	Compliance with Authority Required procedures - Streamlined Authority Code 14240
C14242	P14242	CN14242	Alendronic acid	Osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; Patient must be aged 70 years or older; Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p>	
C14244	P14244	CN14244	Trandolapril with verapamil	<p>Hypertension</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must not be for the initiation of anti-hypertensive therapy; AND</p> <p>The condition must be inadequately controlled with an ACE inhibitor. or</p> <p>The condition must be inadequately controlled with verapamil.</p>	
C14245	P14245	CN14245	Lercanidipine with enalapril Perindopril with amlodipine Ramipril with felodipine	<p>Hypertension</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must not be for the initiation of anti-hypertensive therapy; AND</p> <p>The condition must be inadequately controlled with an ACE inhibitor. or</p> <p>The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.</p>	
C14246	P14246	CN14246	Perindopril with amlodipine	<p>Stable coronary heart disease</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must not be for the initiation of therapy for coronary heart disease; AND</p> <p>The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.</p>	
C14249	P14249	CN14249	Ezetimibe	<p>Hypercholesterolaemia</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>The treatment must be co-administered with an HMG CoA reductase inhibitor (statin); AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14249</p>

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				<p>Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND</p> <p>Patient must have coronary heart disease. or</p> <p>Patient must have cerebrovascular disease. or</p> <p>Patient must have peripheral vascular disease. or</p> <p>Patient must have diabetes mellitus with microalbuminuria. or</p> <p>Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or</p> <p>Patient must have diabetes mellitus and be aged 60 years or more. or</p> <p>Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or</p> <p>Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or</p> <p>Patient must have heterozygous familial hypercholesterolaemia.</p> <p>Patient must have homozygous familial hypercholesterolaemia. or</p> <p>Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or</p> <p>Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.</p> <p>The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.</p> <p>The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.</p> <p>Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.</p>	
C14251	P14251	CN14251	Bisoprolol Carvedilol	<p>Moderate to severe heart failure</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Metoprolol succinate Nebivolol	Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.	
C14254	P14254	CN14254	Sacubitril with valsartan	<p>Chronic heart failure</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must be symptomatic with NYHA classes II, III or IV; AND</p> <p>Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND</p> <p>Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker:</p> <p>(i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker; AND</p> <p>Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; or</p> <p>Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND</p> <p>The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14254
C14255	P14255	CN14255	Candesartan with hydrochlorothiazide Irbesartan with hydrochlorothiazide Olmesartan with hydrochlorothiazide Telmisartan with hydrochlorothiazide	<p>Hypertension</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must not be for the initiation of anti-hypertensive therapy; AND</p> <p>The condition must be inadequately controlled with an angiotensin II antagonist. or</p> <p>The condition must be inadequately controlled with a thiazide diuretic.</p>	

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			Valsartan with hydrochlorothiazide		
C14257	P14257	CN14257	Amlodipine with valsartan Olmesartan with amlodipine Telmisartan with amlodipine	Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist. or The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.	
C14259	P14259	CN14259	Calcitriol	Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	Compliance with Authority Required procedures - Streamlined Authority Code 14259
C14260	P14260	CN14260	Mesalazine	Ulcerative colitis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C14263	P14263	CN14263	Risedronic acid	Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	
C14264	P14264	CN14264	Apixaban Rivaroxaban	Deep vein thrombosis Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have confirmed acute symptomatic deep vein thrombosis; AND Patient must not have symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 14264
C14266	P14266	CN14266	Eplerenone	Heart failure with a left ventricular ejection fraction of 40% or less The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must occur within 3 to 14 days following an acute myocardial infarction; AND The treatment must be commenced within 14 days of an acute myocardial infarction. The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 14266
C14267	P14267	CN14267	Perindopril with indapamide	Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor. or The condition must be inadequately controlled with a thiazide-like diuretic.	
C14269	P14269	CN14269	Ezetimibe with atorvastatin Ezetimibe with simvastatin	Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	Compliance with Authority Required procedures -

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				<p>The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; AND Patient must have coronary heart disease. or Patient must have cerebrovascular disease. or Patient must have peripheral vascular disease. or Patient must have diabetes mellitus with microalbuminuria. or Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or Patient must have diabetes mellitus and be aged 60 years or more. or Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or Patient must have heterozygous familial hypercholesterolaemia. Patient must have homozygous familial hypercholesterolaemia. or Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or A clinically important product-related adverse event is defined as follows (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</p>	Streamlined Authority Code 14269

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.</p> <p>The type and severity of the adverse event or contraindication must be documented in the patient's medical records.</p>	
C14270	P14270	CN14270	Carvedilol	<p>Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	
C14272	P14272	CN14272	<p>Amlodipine with valsartan and hydrochlorothiazide</p> <p>Olmesartan with amlodipine and hydrochlorothiazide</p>	<p>Hypertension</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must not be for the initiation of anti-hypertensive therapy; AND</p> <p>The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.</p>	
C14274	P14274	CN14274	Raloxifene	<p>Established post-menopausal osteoporosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p> <p>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14274</p>
C14275	P14275	CN14275	Adapalene with benzoyl peroxide	<p>Severe acne vulgaris</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be maintenance therapy.	
C14280	P14280	CN14280	Enalapril with hydrochlorothiazide	Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor. or The condition must be inadequately controlled with a thiazide diuretic.	
C14283	P14283	CN14283	Ezetimibe	Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; or Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; or Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated; AND Patient must have coronary heart disease. or Patient must have cerebrovascular disease. or Patient must have peripheral vascular disease. or Patient must have diabetes mellitus with microalbuminuria. or Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or Patient must have diabetes mellitus and be aged 60 years or more. or Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or Patient must have heterozygous familial hypercholesterolaemia. Patient must have homozygous familial hypercholesterolaemia. or Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease	Compliance with Authority Required procedures - Streamlined Authority Code 14283

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or A clinically important product-related adverse event is defined as follows (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.	
C14284	P14284	CN14284	Ezetimibe and rosuvastatin Ezetimibe with atorvastatin Ezetimibe with simvastatin	Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND Patient must have coronary heart disease. or Patient must have cerebrovascular disease. or Patient must have peripheral vascular disease. or Patient must have diabetes mellitus with microalbuminuria. or Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or Patient must have diabetes mellitus and be aged 60 years or more. or Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or	Compliance with Authority Required procedures - Streamlined Authority Code 14284

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				<p>Patient must have heterozygous familial hypercholesterolaemia. Patient must have homozygous familial hypercholesterolaemia. or Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.</p>	
C14287	P14287	CN14287	Calcitriol	<p>Hypoparathyroidism The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14287
C14289	P14289	CN14289	Moxonidine	<p>Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be receiving concurrent antihypertensive therapy.</p>	
C14291	P14291	CN14291	Alendronic acid	<p>Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	
C14296	P14296	CN14296	Calcitriol	Vitamin D-resistant rickets The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 14296
C14298	P14298	CN14298	Rivaroxaban	Chronic stable atherosclerotic disease Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 14298
C14300	P14300	CN14300	Apixaban Rivaroxaban	Prevention of recurrent venous thromboembolism Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have a history of venous thromboembolism.	Compliance with Authority Required procedures - Streamlined Authority Code 14300
C14301	P14301	CN14301	Rivaroxaban	Prevention of stroke or systemic embolism The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have non-valvular atrial fibrillation; AND Patient must have one or more risk factors for developing stroke or systemic embolism. Risk factors for developing stroke or systemic ischaemic embolism are	Compliance with Authority Required procedures - Streamlined Authority Code 14301

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism; (ii) age 75 years or older; (iii) hypertension; (iv) diabetes mellitus; (v) heart failure and/or left ventricular ejection fraction 35% or less.	
C14302	P14302	CN14302	Apixaban	Pulmonary embolism Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have confirmed acute symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 14302
C14305	P14305	CN14305	Atenolol	For a patient who is unable to take a solid dose form of atenolol. The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C14306	P14306	CN14306	Balsalazide	Ulcerative colitis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had a documented hypersensitivity reaction to a sulphonamide. or Patient must be intolerant to sulfasalazine.	Compliance with Authority Required procedures - Streamlined Authority Code 14306
C14308	P14308	CN14308	Apixaban Dabigatran etexilate	Prevention of stroke or systemic embolism The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have non-valvular atrial fibrillation; AND Patient must have one or more risk factors for developing stroke or systemic embolism. Risk factors for developing stroke or systemic ischaemic embolism are (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism; (ii) age 75 years or older; (iii) hypertension;	Compliance with Authority Required procedures - Streamlined Authority Code 14308

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(iv) diabetes mellitus; (v) heart failure and/or left ventricular ejection fraction 35% or less.	
C14309	P14309	CN14309	Alendronic acid	Corticosteroid-induced osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.	
C14310	P14310	CN14310	Ezetimibe	Hypercholesterolaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have homozygous sitosterolaemia.	Compliance with Authority Required procedures - Streamlined Authority Code 14310
C14311	P14311	CN14311	Valsartan with hydrochlorothiazide	Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist. or The condition must be inadequately controlled with a thiazide diuretic.	
C14313	P14313	CN14313	Febuxostat	Chronic gout The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be either chronic gouty arthritis or chronic tophaceous gout; AND Patient must have a medical contraindication to allopurinol. or Patient must have a documented history of allopurinol hypersensitivity syndrome. or	Compliance with Authority Required procedures - Streamlined Authority Code 14313

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				Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.	
C14318	P14318	CN14318	Rivaroxaban	Pulmonary embolism Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have confirmed acute symptomatic pulmonary embolism.	Compliance with Authority Required procedures - Streamlined Authority Code 14318
C14319	P14319	CN14319	Thiamine	Thiamine deficiency The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be for prophylaxis; Patient must be an Aboriginal or a Torres Strait Islander person.	Compliance with Authority Required procedures - Streamlined Authority Code 14319
C14322	P14322	CN14322	Calcitriol	Hypocalcaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be due to renal disease.	Compliance with Authority Required procedures - Streamlined Authority Code 14322
C14323	P14323	CN14323	Azacitidine	Acute Myeloid Leukaemia Dose escalation therapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have, in order to extend the dose schedule as per the TGA-approved Product Information, between 5% to 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, in conjunction with clinical assessment; AND Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin. Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail If the application is submitted through HPOS form upload or mail, it must include (a) a completed authority prescription form; and	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)</p> <p>(c) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating the blast percentage.</p> <p>All reports must be documented in the patient's medical records.</p>	
C14324	P14324	CN14324	Pembrolizumab	<p>Recurrent, unresectable or metastatic triple negative breast cancer</p> <p>The condition must have been (up until this drug therapy) untreated in the unresectable/metastatic disease stage; AND</p> <p>The condition must have been (up until this drug therapy) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy in breast cancer; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND</p> <p>The treatment must be in combination with chemotherapy; AND</p> <p>The condition must have both:</p> <p>(i) programmed cell death ligand 1 (PD-L1) expression confirmed by a validated test, (ii) a Combined Positive Score (CPS) of at least 10 at treatment initiation; AND</p> <p>Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; or</p> <p>Patient must be undergoing continuing treatment with this drug - both the following are true:</p> <p>(i) the condition has not progressed on active treatment with this drug, (ii) this prescription does not extend PBS subsidy beyond 24 cumulative months from the first administered dose; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14324
C14326	P14326	CN14326	Obinutuzumab	<p>Chronic lymphocytic leukaemia (CLL)</p> <p>Combination use with chlorambucil only</p>	Compliance with Authority Required procedures -

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				<p>The condition must be CD20 positive; AND The condition must be previously untreated; AND The treatment must be in combination with chlorambucil; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition. Treatment must be discontinued in patients who experience disease progression whilst on this treatment.</p>	Streamlined Authority Code 14326
C14327	P14327	CN14327	Patiromer	<p>Chronic hyperkalaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not be in place of emergency treatment of hyperkalaemia; AND Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; AND Patient must not be undergoing dialysis.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14327
C14332	P14332	CN14332	Azacitidine	<p>Acute Myeloid Leukaemia Treatment following intensive induction chemotherapy - Initial treatment Patient must have demonstrated either: (i) first complete remission, (ii) complete remission with incomplete blood count recovery following intensive induction chemotherapy; AND Patient must not be a candidate for, including those who choose not to proceed to, haematopoietic stem cell transplantation; AND Patient must have, at the time of induction therapy, a cytogenetic risk classified as either: (i) intermediate-risk, (ii) poor-risk; AND Patient must not have undergone a stem cell transplant; AND Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin. A complete remission is defined as bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>count greater than $1.0 \times 10^9/L$ and platelet count greater than or equal to $100 \times 10^9/L$.</p> <p>A complete remission with incomplete blood count recovery is defined as bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count less than $1.0 \times 10^9/L$ or platelet count less than $100 \times 10^9/L$.</p>	
C14337	P14337	CN14337	Zanubrutinib	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First line drug treatment of this indication The condition must be untreated with drug treatment at the time of the first dose of this drug; or Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug. or Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.</p>	Compliance with Authority Required procedures
C14338	P14338	CN14338	Azacitidine	<p>Acute Myeloid Leukaemia Treatment following intensive induction chemotherapy - Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood; AND Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.</p>	Compliance with Authority Required procedures

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C14340	P14340	CN14340	Venetoclax	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Initial treatment in first-line therapy - Dose titration (weeks 1 to 4 of a 5-week ramp-up schedule) The condition must be untreated with drug treatment at the time of the first dose of this drug; or Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses).</p>	Compliance with Authority Required procedures
C14342	P14342	CN14342	Patiromer	<p>Chronic hyperkalaemia Initial PBS-subsidised treatment (including grandfathered patients) Patient must have stage 3 to stage 4 chronic kidney disease; The condition must be inadequately controlled by a low potassium diet; AND Patient must have experienced at least 2 episodes of hyperkalaemia (defined as serum potassium levels of at least 6.0 mmol/L) within the 12 months prior to commencing this drug; AND The treatment must not be in place of emergency treatment of hyperkalaemia; AND Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; or Patient must be indicated for treatment with a renin angiotensin aldosterone system inhibitor, but unable to tolerate this due to prior occurrence of hyperkalaemia; AND Must be treated by a specialist medical practitioner with experience in the diagnosis and management of chronic kidney disease.</p>	Compliance with Authority Required procedures
C14346	P14346	CN14346	Idelalisib	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Initial treatment The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14348	P14348	CN14348	Ezetimibe with atorvastatin	<p>The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition; AND</p> <p>The condition must have relapsed or be refractory to at least one prior therapy; AND</p> <p>The condition must be CD20 positive; AND</p> <p>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.</p> <p>Hypercholesterolaemia</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND</p> <p>Patient must have coronary heart disease. or</p> <p>Patient must have cerebrovascular disease. or</p> <p>Patient must have peripheral vascular disease. or</p> <p>Patient must have diabetes mellitus with microalbuminuria. or</p> <p>Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or</p> <p>Patient must have diabetes mellitus and be aged 60 years or more. or</p> <p>Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or</p> <p>Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or</p> <p>Patient must have heterozygous familial hypercholesterolaemia.</p> <p>Patient must have homozygous familial hypercholesterolaemia. or</p> <p>Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14348</p>

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C14350	P14350	CN14350	Ezetimibe and rosuvastatin	<p>Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or</p> <p>Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.</p> <p>The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.</p> <p>The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.</p> <p>Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.</p> <p>Hypercholesterolaemia</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND</p> <p>Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; AND</p> <p>Patient must have coronary heart disease. or</p> <p>Patient must have cerebrovascular disease. or</p> <p>Patient must have peripheral vascular disease. or</p> <p>Patient must have diabetes mellitus with microalbuminuria. or</p> <p>Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or</p> <p>Patient must have diabetes mellitus and be aged 60 years or more. or</p> <p>Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or</p> <p>Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or</p> <p>Patient must have heterozygous familial hypercholesterolaemia.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14350

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14359	P14359	CN14359	Infliximab	<p>Patient must have homozygous familial hypercholesterolaemia. or Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or A clinically important product-related adverse event is defined as follows (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. The type and severity of the adverse event or contraindication must be documented in the patient's medical records.</p> <p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30</p>	Compliance with Written Authority Required procedures

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				<p>mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following <ul style="list-style-type: none"> (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14360	P14360	CN14360	Infliximab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14362	P14362	CN14362	Lenalidomide	<p>Relapsed and/or refractory multiple myeloma</p> <p>Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone</p> <p>Patient must be undergoing concurrent treatment with carfilzomib obtained through the PBS; AND</p> <p>Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.</p>	Compliance with Authority Required procedures
C14363	P14363	CN14363	Carfilzomib	<p>Relapsed and/or refractory multiple myeloma</p>	Compliance with Authority Required

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				<p>Continuing treatment for Cycles 3 to 12 Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	<p>procedures - Streamlined Authority Code 14363</p>
C14364	P14364	CN14364	Carfilzomib	<p>Relapsed and/or refractory multiple myeloma Continuing treatment for Cycles 13 onwards Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. Progressive disease is defined as at least 1 of the following</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14364</p>

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				(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.	
C14366	P14366	CN14366	Somatropin	Severe growth hormone deficiency Continuing treatment in a person with a mature skeleton or aged 18 years or older Must be treated by an endocrinologist; AND Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause in a patient with a mature skeleton. or Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease in a patient with chronological age of 18 years or older. or Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years.	Compliance with Authority Required procedures

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C14368	P14368	CN14368	Risdiplam	<p>Spinal muscular atrophy (SMA)</p> <p>Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood</p> <p>Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood;</p> <p>Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised);</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; or</p> <p>Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access); AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are</p> <ul style="list-style-type: none"> (i) Failure to meet or regression in ability to perform age-appropriate motor milestones, (ii) Proximal weakness, (iii) Hypotonia, (iv) Absence of deep tendon reflexes, (v) Failure to gain weight appropriate for age, (vi) Any active denervation or chronic neurogenic changes found on electromyography, (vii) A compound muscle action potential below normative values for an age-matched child. <p>In this authority application, confirm</p> <ul style="list-style-type: none"> (1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy, (2) which of the above (i to vii) (at least 1) were present during childhood, (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed. 	
C14370	P14370	CN14370	Nusinersen	<p>Spinal muscular atrophy (SMA)</p> <p>Changing the prescribed therapy</p> <p>Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND</p>	Compliance with Written Authority Required procedures

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C14372	P14372	CN14372	Risdiplam	<p>Patient must be untreated with gene therapy; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.</p> <p>Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA) Initial treatment The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND Patient must be untreated with gene therapy; Patient must be 18 years of age or under. Defined signs and symptoms of type I SMA are i) Onset before 6 months of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child. Defined signs and symptoms of type II SMA are i) Onset between 6 and 18 months; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Weakness in trunk righting/derotation; or v) Hypotonia; or vi) Absence of deep tendon reflexes; or vii) Failure to gain weight appropriate for age; or viii) Any active chronic neurogenic changes; or ix) A compound muscle action potential below normative values for an age-matched child. Defined signs and symptoms of type IIIa SMA are i) Onset between 18 months and 3 years of age; and ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or iii) Proximal weakness; or iv) Hypotonia; or v) Absence of deep tendon reflexes; or vi) Failure to gain weight appropriate for age; or vii) Any active chronic neurogenic changes; or viii) A compound muscle action potential below normative values for an age-matched child.</p>	

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Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>Application for authorisation of initial treatment must be in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following</p> <p>(ii) sign(s) and symptom(s) that the patient has experienced; and</p> <p>(iii) patient's age at the onset of sign(s) and symptom(s).</p> <p>i) specification of SMA type (I, II or IIIa); and</p> <p>(ii) sign(s) and symptom(s) that the patient has experienced; and</p> <p>(iii) patient's age at the onset of sign(s) and symptom(s).</p> <p>The approved Product Information recommended dosing is as follows</p> <p>(i) 16 days to less than 2 months of age 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient.</p> <p>Based on (i) to (iv), prescribe up to</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p> <p>3 units where (iii) applies;</p> <p>3 units where (iv) applies.</p>	
C14374	P14374	CN14374	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14375	P14375	CN14375	Bimekizumab	Severe chronic plaque psoriasis Continuing treatment, Whole body	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	

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C14376	P14376	CN14376	Bimekizumab	<p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Severe chronic plaque psoriasis Continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14377	P14377	CN14377	Adalimumab	<p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age;</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14378	P14378	CN14378	Adalimumab	<p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14382	P14382	CN14382	Etanercept	<p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14384	P14384	CN14384	Deucravacitinib	<p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>Severe chronic plaque psoriasis</p> <p>Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; or</p> <p>Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; or</p> <p>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND</p> <p>The condition must have caused significant interference with quality of life; AND</p> <p>Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of:</p> <p>(i) a biological medicine, (ii) ciclosporin, (iii) apremilast; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14384</p>

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				<p>Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; or</p> <p>Must be treated by a general practitioner who has been directed to continue treatment (not initiate treatment) by one of the above practitioner types; Patient must be at least 18 years of age.</p>	
C14387	P14387	CN14387	Fosnetupitant with palonosetron	<p>Nausea and vomiting</p> <p>The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy; AND</p> <p>The treatment must be in combination with dexamethasone, unless contraindicated; AND</p> <p>Patient must be unable to swallow. or</p> <p>Patient must be contraindicated to oral anti-emetics.</p>	Compliance with Authority Required procedures
C14389	P14389	CN14389	Carfilzomib	<p>Relapsed and/or refractory multiple myeloma</p> <p>Initial treatment for Cycles 1 to 3</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>The treatment must be in combination with lenalidomide and dexamethasone; AND</p> <p>Patient must have progressive disease after at least one prior therapy; AND</p> <p>Patient must not have previously received this drug for this condition.</p> <p>Progressive disease is defined as at least 1 of the following</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14389

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14390	P14390	CN14390	Somatropin	<p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Provide details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of the most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response once only through the Authority application for lenalidomide.</p> <p>Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child Must be treated by an endocrinologist; AND Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child; AND Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; or Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; or Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre; Patient must have a mature skeleton. Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency. The authority application must be in writing and must include: A completed authority prescription form; AND A completed Severe Growth Hormone Deficiency supporting information form; AND</p>	Compliance with Written Authority Required procedures

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C14392	P14392	CN14392	Risdiplam	<p>Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.</p> <p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; or Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing. The approved Product Information recommended dosing is as follows (i) 16 days to less than 2 months of age 0.15 mg/kg (ii) 2 months to less than 2 years of age 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more 5 mg In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to 1 unit where (i) applies;</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.	
C14396	P14396	CN14396	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological</p>	Compliance with Written Authority Required procedures

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				<p>medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following <ul style="list-style-type: none"> (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14398	P14398	CN14398	Adalimumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p>	

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				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14399	P14399	CN14399	Adalimumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include (1) a completed authority prescription form(s); and</p>	

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				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14400	P14400	CN14400	Guselkumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 20 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older;</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p>	

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				<p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following <ul style="list-style-type: none"> (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14403	P14403	CN14403	Pembrolizumab	<p>Advanced carcinoma of the cervix</p> <p>Initial treatment</p> <p>The condition must be at least one of (i) persistent carcinoma, (ii) recurrent carcinoma, (iii) metastatic carcinoma of the cervix; AND</p> <p>The condition must be unsuitable for curative treatment with either of (i) surgical resection, (ii) radiation; AND</p> <p>Patient must have WHO performance status no higher than 1; AND</p> <p>Patient must not have received prior treatment for this PBS indication; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14403</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be undergoing concomitant treatment with chemotherapy, containing a minimum of:</p> <p>(i) a platinum-based chemotherapy agent, plus (ii) paclitaxel; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	
C14404	P14404	CN14404	Pembrolizumab	<p>Advanced carcinoma of the cervix</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a total of (i) 24 months, (ii) 35 doses (based on a 3-weekly dose regimen), (iii) 17 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless if it was PBS/non-PBS subsidised; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14404
C14405	P14405	CN14405	Pembrolizumab	<p>Advanced carcinoma of the cervix</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 October 2023; AND</p> <p>Patient must have met all other PBS eligibility criteria that a non-Grandfather patient would ordinarily be required to meet, meaning that at the time non-PBS supply was commenced, the patient:</p> <p>(i) had either one of (1) persistent carcinoma, (2) recurrent carcinoma, (3) metastatic carcinoma of the cervix; (ii) had a WHO performance status no higher than 1; (iii) was unsuitable for curative treatment with either of (1) surgical resection, (2) radiation; (iv) had not received prior treatment for this PBS indication; (v) was treated concomitantly with platinum-based chemotherapy agent, plus paclitaxel; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14405

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C14408	P14408	CN14408	Risdiplam	<p>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a total of (i) 24 months, (ii) 35 doses (based on a 3-weekly dose regimen), (iii) 17 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless if it was PBS/non-PBS subsidised; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.</p> <p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)</p> <p>Initial PBS-subsidised treatment with this drug in a child</p> <p>Patient must be of an age that is prior to their 19th birthday at the time of this authority application;</p> <p>Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC);</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; or</p> <p>Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access); AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are (i) Failure to meet or regression in ability to perform age-appropriate motor milestones, (ii) Proximal weakness, (iii) Hypotonia, (iv) Absence of deep tendon reflexes, (v) Any active denervation or chronic neurogenic changes found on electromyography, (vi) A compound muscle action potential below normative values for an age-matched child. In this authority application, confirm (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy, (2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday, (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed. The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing. The approved Product Information recommended dosing is as follows (i) 16 days to less than 2 months of age 0.15 mg/kg (ii) 2 months to less than 2 years of age 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg 0.25 mg/kg</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(iv) 2 years of age and older weighing 20 kg or more 5 mg In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to 1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.</p>	
C14412	P14412	CN14412	Bimekizumab	<p>Severe chronic plaque psoriasis Grandfathered patient - Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Patient must have a documented severe chronic plaque psoriasis where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023; AND Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND Patient must have a documented Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. An adequate response to treatment is defined as</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14415	P14415	CN14415	Ustekinumab	<p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and</p> <p>(c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14416	P14416	CN14416	Enfortumab vedotin	<p>Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer</p> <p>The condition must have progressed on/following both:</p> <p>(i) platinum-based chemotherapy, (ii) programmed cell death 1/ligand 1 (PD-1/PD-L1) inhibitor therapy; or</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14416</p>

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				<p>The condition must have progressed on/following platinum-based chemotherapy, whilst PD-1/PD-L1 inhibitor therapy resulted in an intolerance that required treatment cessation; AND</p> <p>Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND</p> <p>Patient must be undergoing treatment with this drug for the first time. or</p> <p>Patient must be undergoing continuing treatment with this drug, with each of the following being true:</p> <p>(i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.</p>	
C14417	P14417	CN14417	Apremilast	<p>Severe chronic plaque psoriasis</p> <p>Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; or</p> <p>Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; or</p> <p>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND</p> <p>The condition must have caused significant interference with quality of life; AND</p> <p>Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of:</p> <p>(i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib; AND</p> <p>Must be treated by a medical practitioner who is either:</p> <p>(i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; or</p> <p>Must be treated by a general practitioner who has been directed to continue treatment (not initiate treatment) by one of the above practitioner types;</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14417
C14420	P14420	CN14420	Risdiplam	<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment in an adult where treatment was initiated in adulthood</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; or</p> <p>Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND</p> <p>The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; or</p> <p>The treatment must be occurring within the first 104 weeks from the first administered dose; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.</p> <p>A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.</p> <p>PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.</p> <p>Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.</p>	

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				In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HF MSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).	
C14421	P14421	CN14421	Nusinersen	<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)</p> <p>Changing the prescribed therapy</p> <p>Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND</p> <p>Patient must be untreated with gene therapy; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.</p>	Compliance with Written Authority Required procedures
C14425	P14425	CN14425	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p>	

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				<p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14427	P14427	CN14427	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin</p>	Compliance with Written Authority Required procedures

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				<p>at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p>	

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				<p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14428	P14428	CN14428	Guselkumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 20 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older;</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p>	

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				<p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14430	P14430	CN14430	Secukinumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older;</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological</p>	

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				<p>medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14431	P14431	CN14431	Somatropin	<p>Severe growth hormone deficiency</p> <p>Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child</p> <p>Must be treated by an endocrinologist; AND</p> <p>Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child;</p> <p>Patient must have a mature skeleton.</p> <p>Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.</p> <p>The authority application must be in writing and must include:</p> <p>A completed authority prescription form; AND</p> <p>A completed Severe Growth Hormone Deficiency supporting information form.</p>	Compliance with Written Authority Required procedures
C14433	P14433	CN14433	Nusinersen	<p>Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14435	P14435	CN14435	Risdiplam	<p>hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>Spinal muscular atrophy (SMA)</p> <p>Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with Type 1 SMA</p> <p>Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this:</p> <p>(i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples); AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND</p> <p>Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type;</p>	Compliance with Authority Required procedures

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				<p>Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.</p> <p>Confirm that a previous PBS authority application has been approved for symptomatic Type 1 SMA.</p> <p>Definition</p> <p>Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.</p> <ul style="list-style-type: none"> 0. Absence of developmental states (1 to 9) listed below <ul style="list-style-type: none"> 1. Rolls from side to side on back; 2. Child holds head erect for at least 3 seconds unsupported; 3. Sitting, but with assistance; 4. Sitting without assistance <ul style="list-style-type: none"> (a) Child sits up straight with the head erect for at least 10 seconds; (b) Child does not use arms or hands to balance body or support position. 5. Hands and knees crawling <ul style="list-style-type: none"> (a) Child alternately moves forward or backwards on hands and knees; (b) The stomach does not touch the supporting surface; (c) There are continuous and consecutive movements at least 3 in a row. 6. Standing with assistance <ul style="list-style-type: none"> (a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object; (b) The body does not touch the stable object, and the legs support most of the body weight; (c) Child thus stands with assistance for at least 10 seconds. 	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>7. Standing alone</p> <p>(a) Child stands in upright position on both feet (not on the toes) with the back straight;</p> <p>(b) The leg supports 100% of the child's weight;</p> <p>(c) There is no contact with a person or object;</p> <p>(d) Child stands alone for at least 10 seconds.</p> <p>8. Walking with assistance</p> <p>(a) Child is in an upright position with the back straight;</p> <p>(b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;</p> <p>(c) One leg moves forward while the other supports part of the body weight;</p> <p>(d) Child takes at least 5 steps in this manner.</p> <p>9. Walking alone</p> <p>(a) Child takes at least 5 steps independently in upright position with the back straight;</p> <p>(b) One leg moves forward while the other supports most of the body weight;</p> <p>(c) There is no contact with a person or object.</p> <p>Confirm which developmental state has regressed by (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i)).</p> <p>Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.</p> <p>The approved Product Information recommended dosing is as follows</p> <p>(i) 16 days to less than 2 months of age 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient.</p> <p>Based on (i) to (iv), prescribe up to</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p>	

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C14437	P14437	CN14437	Bimekizumab	<p>3 units where (iii) applies; 3 units where (iv) applies.</p> <p>Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a dermatologist. An adequate response to treatment is defined as A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14440	P14440	CN14440	Risankizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p>	Compliance with Written Authority Required procedures

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				<p>The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14442	P14442	CN14442	Ustekinumab	<p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older;</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following <ul style="list-style-type: none"> (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. <p>At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14443	P14443	CN14443	Netupitant with Palonosetron	<p>Nausea and vomiting</p> <p>The treatment must be in combination with dexamethasone, unless contraindicated; AND</p> <p>The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14443
C14448	P14448	CN14448	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless</p>	

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C14449	P14449	CN14449	Bimekizumab	<p>the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 24 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 24 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 24 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 24 weeks treatment; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND</p>	Compliance with Authority Required procedures

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C14453	P14453	CN14453	Ixekizumab	<p>Must be treated by a dermatologist.</p> <p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older;</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14454	P14454	CN14454	Risankizumab	<p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	

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C14458	P14458	CN14458	Risdiplam	<p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.</p> <p>Pre-symptomatic spinal muscular atrophy (SMA) Initial treatment with this drug of pre-symptomatic spinal muscular atrophy (SMA) Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND The condition must be pre-symptomatic; AND The treatment must be given concomitantly with best supportive care for this condition; AND Patient must be untreated with gene therapy; Patient must be aged under 36 months prior to commencing treatment. Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include: (a) a completed authority prescription form; and (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following: (i) confirmation of genetic diagnosis of SMA; and</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14459	P14459	CN14459	Nusinersen	<p>(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p> <p>The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows</p> <p>(i) 16 days to less than 2 months of age 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to</p> <p>1 unit where (i) applies;</p> <p>2 units where (ii) applies;</p> <p>3 units where (iii) applies;</p> <p>3 units where (iv) applies.</p> <p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment in an adult where treatment was initiated in adulthood</p> <p>The treatment must be each of:</p> <p>(i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; or</p> <p>The treatment must be occurring within the first 104 weeks from the first administered dose; AND</p> <p>Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or</p> <p>Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14460	P14460	CN14460	Bimekizumab	<p>Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; AND</p> <p>Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.</p> <p>Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response. A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.</p> <p>PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.</p> <p>Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.</p> <p>In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be at least 18 years of age; Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include (1) a completed authority prescription form(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14461	P14461	CN14461	Ixekizumab	<p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14462	P14462	CN14462	Secukinumab	<p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Face, hand, foot (new patient)</p> <p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30</p>	Compliance with Written Authority Required procedures

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				<p>mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older;</p> <p>Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following <ul style="list-style-type: none"> (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>	
C14464	P14464	CN14464	Tildrakizumab	<p>Severe chronic plaque psoriasis</p> <p>Initial treatment - Initial 1, Whole body (new patient)</p> <p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14465	P14465	CN14465	Tildrakizumab	<p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.</p> <p>Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments:</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; Must be treated by a dermatologist.</p> <p>Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.</p>	

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C14468	P14468	CN14468	Onasemnogene abeparvovec	<p>Spinal muscular atrophy (SMA)</p> <p>Use in a patient untreated with disease modifying therapies for this condition</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Must be treated in a treatment centre that is each of:</p> <p>(i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND</p> <p>Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of:</p> <p>(i) nusinersen, (ii) risdiplam;</p> <p>Patient must be no older than 9 months of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14469	P14469	CN14469	Onasemnogene abeparvec	<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.</p> <p>Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:</p> <p>(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.</p> <p>Confirm that there is a genetic test finding that substantiates the number of SMN2 gene copies to be 3 and has been determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).</p> <p>Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.</p> <p>Spinal muscular atrophy (SMA)</p> <p>Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvec)</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND</p> <p>Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition; AND</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Must be treated in a treatment centre that is each of:</p> <p>(i) recognised in the management of SMA, (ii) accredited in the use of this gene</p>	Compliance with Authority Required procedures

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C14470	P14470	CN14470	Trastuzumab deruxtecan	<p>technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased; Patient must be no older than 9 months of age; Patient must have symptomatic Type 1 SMA. or Patient must have pre-symptomatic SMA. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA. Confirm that a previous PBS authority application has been approved for one of the following (i) Symptomatic Type 1 SMA; or (ii) Pre-symptomatic SMA. State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials. Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must have, at the time of treatment initiation with this drug, progressed during/within 6 months following adjuvant treatment with a HER2 directed therapy; AND Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only; AND Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions. or Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions. Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription 1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable). 2) Details of prior HER2 directed drug regimens prescribed for the patient. 3) Cardiac function test results (evidence obtained in relation to past PBS treatment is acceptable).</p>	
C14471	P14471	CN14471	Dapagliflozin Empagliflozin	<p>Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%; AND Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy); AND Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14471

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				<p>echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause; AND</p> <p>Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.</p>	
C14472	P14472	CN14472	Fremanezumab	<p>Treatment-resistant migraine</p> <p>Initial treatment</p> <p>Must be treated by a neurologist; AND</p> <p>Patient must not be undergoing concurrent treatment with the following PBS benefits:</p> <p>(i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication; AND</p> <p>Patient must have experienced at least 8 migraine headache days per month, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND</p> <p>Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND</p> <p>Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug;</p> <p>Patient must be at least 18 years of age.</p> <p>Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.</p> <p>Patient must have the number of migraine headache days per month documented in their medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14472
C14476	P14476	CN14476	Ravulizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Subsequent Continuing Treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND</p> <p>Patient must have experienced clinical improvement as a result of treatment with this drug; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have experienced a stabilisation of the condition as a result of treatment with this drug; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.</p>	
C14477	P14477	CN14477	Ravulizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH)</p> <p>Initial treatment - Initial 1 (new patient) induction dose</p> <p>Patient must not have received prior treatment with this drug for this condition; AND</p> <p>Patient must have a diagnosis of PNH established by flow cytometry; AND</p> <p>Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND</p> <p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; or</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; or</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; or</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; or</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; or</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded; or</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14483	P14483	CN14483	Adalimumab Baricitinib Etanercept Tocilizumab Tofacitinib Upadacitinib	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p>	Compliance with Written Authority Required procedures

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				<p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks,</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14485	P14485	CN14485	Tocilizumab	<p>immediately following the second infusion, before swapping to an alternate biological medicine.</p> <p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14485</p>

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C14486	P14486	CN14486	Adalimumab Baricitinib Etanercept Tocilizumab Tofacitinib Upadacitinib	<p>number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14487	P14487	CN14487	Tocilizumab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either:</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due</p>	<p>Compliance with Written Authority Required procedures</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <ol style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless</p>	

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				<p>the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14488	P14488	CN14488	<p>Abatacept</p> <p>Adalimumab</p> <p>Baricitinib</p> <p>Etanercept</p> <p>Golimumab</p> <p>Tocilizumab</p> <p>Tofacitinib</p> <p>Upadacitinib</p>	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
C14489	P14489	CN14489	Tocilizumab	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p>	

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C14491	P14491	CN14491	Tocilizumab	<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints</p>	

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				<p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14493	P14493	CN14493	Adalimumab Baricitinib Certolizumab pegol Etanercept Tocilizumab Tofacitinib	<p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include</p>	Compliance with Written Authority Required procedures

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				<p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14496	P14496	CN14496	Adalimumab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following:</p> <p>(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or</p> <p>Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a</p>	

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				<p>severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the active joint count, ESR and/or CRP result and date of results;</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14498	P14498	CN14498	Adalimumab Baricitinib Etanercept Tocilizumab Tofacitinib Upadacitinib	<p>(b) details of prior treatment, including dose and date/duration of treatment. (c) If applicable, details of any contraindications/intolerances. (d) If applicable, the maximum tolerated dose of methotrexate. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs:</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:</p> <p>(i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialed at a minimum dose as mentioned above; or</p> <p>Patient must have a contraindication/severe intolerance to each of:</p> <p>(i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p>	

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C14499	P14499	CN14499	Adalimumab Baricitinib Certolizumab pegol Etanercept Tocilizumab Tofacitinib	<p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14499

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14502	P14502	CN14502	Infliximab	<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p>	Compliance with Authority Required procedures

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				<p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:</p> <p>(i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or</p> <p>Patient must have a contraindication/severe intolerance to each of:</p> <p>(i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the active joint count, ESR and/or CRP result and date of results;</p>	

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C14504	P14504	CN14504	Infliximab	<p>(b) details of prior treatment, including dose and date/duration of treatment. (c) If applicable, details of any contraindications/intolerances. (d) If applicable, the maximum tolerated dose of methotrexate. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; or Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14504</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14505	P14505	CN14505	Infliximab	<p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; or Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14505</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>	
C14507	P14507	CN14507	Abatacept Adalimumab Baricitinib Certolizumab pegol Etanercept Golimumab Infliximab Tocilizumab Tofacitinib	Severe active rheumatoid arthritis First continuing treatment - balance of supply Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14508	P14508	CN14508	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose; AND</p> <p>Patient must have demonstrated an adequate response to treatment; AND</p> <p>Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14508
C14509	P14509	CN14509	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Completion of course - treatment covering weeks 16 to 24 (Whole body)</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must be undergoing current PBS-subsidised treatment with this biological medicine, with the intention to complete the remainder of a 24-week treatment course with this biological medicine; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14509

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine, but within 8 weeks of the last administered dose; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 8 weeks of treatment with etanercept under this restriction. An adequate response to treatment is defined as A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The assessment of response to treatment must be documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	
C14513	P14513	CN14513	Etanercept	<p>Severe chronic plaque psoriasis Initial 1 treatment (Whole body) - biological medicine-naive patient Must be treated by a dermatologist; AND Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND</p>	<p>Compliance with Authority Required procedures</p>

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				<p>Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.</p> <p>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy</p> <p>(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) the PASI score that followed each prior therapy trialled;</p> <p>(iv) the date the PASI scores were determined.</p> <p>A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) the PASI score that followed each prior therapy trialled;</p> <p>(iv) the date the PASI scores were determined.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14515	P14515	CN14515	Infliximab	<p>Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.</p> <p>Severe active rheumatoid arthritis</p> <p>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; or</p> <p>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total</p>	Compliance with Written Authority Required procedures

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				<p>number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.</p>	
C14519	P14519	CN14519	Abatacept Golimumab	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This</p>	

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				<p>will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14522	P14522	CN14522	Abatacept	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following:</p> <p>(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs:</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:</p> <p>(i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialed at a minimum dose as mentioned above; or</p> <p>Patient must have a contraindication/severe intolerance to each of:</p> <p>(i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p>	

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				<p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Initial treatment with an I.V. loading dose Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.</p> <p>Initial treatment with no loading dose One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14523	P14523	CN14523	Abatacept	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.</p> <p>Up to a maximum of 4 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
C14524	P14524	CN14524	Abatacept	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either:</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14530	P14530	CN14530	Ravulizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH) Grandfather (transition from non-PBS-subsidised treatment)</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022; AND</p> <p>Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab; AND</p> <p>Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab; AND</p> <p>Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record; AND</p> <p>Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; or</p> <p>Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; or</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; or</p> <p>Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; or</p> <p>Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; or</p> <p>Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; or</p> <p>Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <ul style="list-style-type: none"> (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH ULN ratio (in figures, rounded to one decimal place) must be at least 1.5 	
C14531	P14531	CN14531	Ravulizumab	<p>Paroxysmal nocturnal haemoglobinuria (PNH) First Continuing Treatment</p> <p>Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction; AND</p> <p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.</p>	Compliance with Authority Required procedures

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				<p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <ul style="list-style-type: none"> (i) Haemoglobin (g/L) (ii) Platelets (x10⁹/L) (iii) White Cell Count (x10⁹/L) (iv) Reticulocytes (x10⁹/L) (v) Neutrophils (x10⁹/L) (vi) Granulocyte clone size (%) (vii) Lactate Dehydrogenase (LDH) (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory (ix) the LDH ULN ratio (in figures, rounded to one decimal place) 	
C14534	P14534	CN14534	Teduglutide	<p>Type III Short bowel syndrome with intestinal failure Initial treatment Must be treated by a gastroenterologist; or Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit; AND Patient must have short bowel syndrome with intestinal failure following major surgery; AND Patient must have a history of dependence on parenteral support for at least 12 months; AND Patient must have received a stable parenteral support regimen for at least 3 days per week in the previous 4 weeks; AND Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years; AND The treatment must not exceed 12 months under this restriction; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either</p> <ul style="list-style-type: none"> (i) for a patient of any age, the mean number of days of parenteral support per week (ii) for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg. 	Compliance with Authority Required procedures

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C14538	P14538	CN14538	Tocilizumab	<p>Determine the mean over any given 4 week period prior to this authority application. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i).</p> <p>Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.</p> <p>A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the</p>	Compliance with Written Authority Required procedures

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				<p>condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
C14542	P14542	CN14542	Certolizumab pegol	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; or</p>	Compliance with Authority Required procedures

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C14543	P14543	CN14543	Ustekinumab	<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; AND</p> <p>The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.</p> <p>Severe chronic plaque psoriasis</p> <p>Initial 1 treatment (Whole body) - biological medicine-naive patient</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The authority application must be made in writing and must include</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy</p> <p>(a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy.</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) the PASI score that followed each prior therapy trialled;</p> <p>(iv) the date the PASI scores were determined.</p> <p>A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) the PASI score that followed each prior therapy trialled;</p> <p>(iv) the date the PASI scores were determined.</p> <p>Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.</p>	
C14544	P14544	CN14544	Infliximab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p>	Compliance with Authority Required procedures

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				<p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the active joint count, ESR and/or CRP result and date of result;</p> <p>(b) the most recent biological agent and the date of the last continuing prescription.</p> <p>(c) If applicable, the new baseline scores.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14546	P14546	CN14546	Infliximab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following:</p> <ul style="list-style-type: none">(i) hydroxychloroquine at a dose of at least 200 mg daily;(ii) leflunomide at a dose of at least 10 mg daily;(iii) sulfasalazine at a dose of at least 2 g daily; <p>or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs:</p> <ul style="list-style-type: none">(i) hydroxychloroquine at a dose of at least 200 mg daily;(ii) leflunomide at a dose of at least 10 mg daily;(iii) sulfasalazine at a dose of at least 2 g daily; <p>or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:</p> <ul style="list-style-type: none">(i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or <p>Patient must have a contraindication/severe intolerance to each of:</p> <ul style="list-style-type: none">(i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p>	

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				<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14547	P14547	CN14547	Infliximab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only</p>	

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				<p>an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14548	P14548	CN14548	Infliximab	<p>Severe active rheumatoid arthritis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14552	P14552	CN14552	Etanercept	<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.</p> <p>Severe chronic plaque psoriasis Initial 2 treatment (Face, hand, foot) - Change of treatment Must be treated by a dermatologist; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.</p> <p>(i) there is an absence of an adequate response to that treatment; or</p> <p>(ii) there was an intolerance to that treatment; or</p>	Compliance with Authority Required procedures

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				<p>(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.</p> <p>In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because</p> <p>(i) there is an absence of an adequate response to that treatment; or</p> <p>(ii) there was an intolerance to that treatment; or</p> <p>(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.</p> <p>The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</p>	
C14553	P14553	CN14553	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Initial 4 - Re-treatment (Whole body)</p> <p>Must be treated by a dermatologist; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have a documented history of severe chronic plaque psoriasis of the whole body; AND</p> <p>Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following:</p> <p>(i) a disease flare where the PASI score has worsened (increased) by at least 50%,</p> <p>(ii) the current PASI score has returned above 15; AND</p> <p>Patient must not have failed more than once to achieve an adequate response with etanercept; AND</p> <p>Patient must not receive more than 16 weeks of treatment with etanercept under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14554	P14554	CN14554	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND</p> <p>Patient must not receive more than 16 weeks of treatment with etanercept under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be documented in the patient's medical records.</p> <p>Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be documented in the patient's medical records.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy</p> <p>(a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or</p>	Compliance with Authority Required procedures

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				<p>(b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;</p> <p>(iv) the dates that response assessments were determined.</p> <p>(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);</p> <p>(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.</p> <p>Provide in this authority application, and document in the patient's medical records, each of</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;</p> <p>(iv) the dates that response assessments were determined.</p> <p>(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);</p> <p>(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.</p> <p>Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment</p> <p>(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine. Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.	
C14555	P14555	CN14555	Abatacept	Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Authority Required procedures - Streamlined Authority Code 14555

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				<p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>	
C14556	P14556	CN14556	Golimumab	<p>Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological</p>	

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				<p>medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
C14557	P14557	CN14557	Golimumab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only</p>	

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				<p>an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14558	P14558	CN14558	Ustekinumab	<p>Severe chronic plaque psoriasis</p> <p>Continuing treatment (Whole body) - treatment covering week 28 and onwards</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response to treatment is defined as</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>The assessment of response to treatment must be provided in this application and documented in the patient's medical records.</p> <p>The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.</p>	
C14560	P14560	CN14560	Abatacept	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p>	Compliance with Written Authority Required procedures

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				<p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Initial treatment with an I.V. loading dose Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no</p>	

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				<p>repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.</p> <p>Initial treatment with no loading dose One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14563	P14563	CN14563	Fremanezumab	<p>Treatment-resistant migraine</p> <p>Continuing treatment</p> <p>Must be treated by a neurologist; or</p> <p>Must be treated by a general practitioner in consultation with a neurologist; AND</p> <p>Patient must not be undergoing concurrent treatment with the following PBS benefits:</p> <p>(i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved and maintained at least 50% reduction from baseline in the number of migraine headache days per month; AND</p> <p>Patient must continue to be appropriately managed for medication overuse headache.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14563</p>

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C14565	P14565	CN14565	Ravulizumab	<p>Patient must have the number of migraine headache days per month documented in their medical records.</p> <p>Paroxysmal nocturnal haemoglobinuria (PNH) Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP); AND Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab; AND Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab; AND Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab; AND Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; or Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; or Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; or Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; or Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; or Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m², where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; or Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND</p> <p>Must be treated by a haematologist. or</p> <p>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information</p> <p>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided</p> <p>(i) Haemoglobin (g/L)</p> <p>(ii) Platelets (x10⁹/L)</p> <p>(iii) White Cell Count (x10⁹/L)</p> <p>(iv) Reticulocytes (x10⁹/L)</p> <p>(v) Neutrophils (x10⁹/L)</p> <p>(vi) Granulocyte clone size (%)</p> <p>(vii) Lactate Dehydrogenase (LDH)</p> <p>(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory</p> <p>(ix) the LDH ULN ratio (in figures, rounded to one decimal place) must be at least 1.5</p>	
C14567	P14567	CN14567	Adalimumab	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14567</p>

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				<p>Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14568	P14568	CN14568	Adalimumab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either:</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14571	P14571	CN14571	Certolizumab pegol	<p>equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the active joint count, ESR and/or CRP result and date of result;</p> <p>(b) the most recent biological agent and the date of the last continuing prescription.</p> <p>(c) If applicable, the new baseline scores.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following:</p> <p>(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs:</p> <p>(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:</p> <p>(i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or</p> <p>Patient must have a contraindication/severe intolerance to each of:</p> <p>(i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p>	

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Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14572	P14572	CN14572	Ustekinumab	<p>Severe chronic plaque psoriasis</p> <p>Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND</p> <p>The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; or</p> <p>The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND</p> <p>Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; or</p>	Compliance with Written Authority Required procedures

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Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14573	P14573	CN14573	Ustekinumab	<p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Severe chronic plaque psoriasis</p> <p>Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.</p> <p>Response to preceding supply</p> <p>An adequate response to treatment is defined as</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>Change in therapy</p> <p>If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because</p> <ul style="list-style-type: none"> (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above <ul style="list-style-type: none"> (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. <p>Recommencing therapy</p> <p>If the patient is recommencing therapy, in relation to the last administered dose, state whether there was</p> <ul style="list-style-type: none"> (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. <p>The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</p>	

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14576	P14576	CN14576	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND</p> <p>The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; or</p> <p>The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND</p> <p>Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; or</p> <p>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures
C14577	P14577	CN14577	Etanercept	<p>Severe chronic plaque psoriasis</p> <p>Initial 4 - Re-treatment (face, hand, foot)</p> <p>Must be treated by a dermatologist; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; AND</p> <p>Patient must be undergoing re-treatment with this biological medicine for this PBS indication after an initial adequate response to the most recent treatment course, but has since experienced at least one of the following:</p> <p>(i) all PASI sub-measures (redness, thickness, scaling) are rated as 'moderate' to 'severe', (ii) at least 2 of the 3 PASI sub-measures are rated as 'severe' to 'very severe', (iii) the skin area affected has increased by at least 50% since the last administered dose, (iv) the skin area affected is at least 30% of the total skin area of the face/hand/foot; AND</p> <p>Patient must not have failed more than once to achieve an adequate response with etanercept; AND</p> <p>Patient must not receive more than 16 weeks of treatment with etanercept under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.</p>	
C14581	P14581	CN14581	Etanercept	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following:</p> <p>(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p>	Compliance with Authority Required procedures

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Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the active joint count, ESR and/or CRP result and date of results;</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14582	P14582	CN14582	Etanercept	<p>(b) details of prior treatment, including dose and date/duration of treatment. (c) If applicable, details of any contraindications/intolerances. (d) If applicable, the maximum tolerated dose of methotrexate. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless</p>	

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C14583	P14583	CN14583	Abatacept	<p>the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p> <p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless</p>	

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C14585	P14585	CN14585	Infliximab	<p>the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Initial treatment with an I.V. loading dose Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.</p> <p>Initial treatment with no loading dose One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14585</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or</p> <p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p>	

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C14586	P14586	CN14586	Ravulizumab	<p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p> <p>Paroxysmal nocturnal haemoglobinuria (PNH) Return from PBS-subsidised eculizumab - induction dose Patient must have received prior PBS-subsidised treatment with this drug for this condition; AND Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria; AND The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan; AND Must be treated by a haematologist. or Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14587	P14587	CN14587	Blinatumomab	<p>is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.</p> <p>Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p> <p>Continuing treatment of previously measurable residual disease of Pre-B-cell ALL</p> <p>Must be treated by a physician experienced in the treatment of haematological malignancies; AND</p> <p>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND</p> <p>Patient must have achieved a complete remission; AND</p> <p>The condition must be negative for measurable residual disease using the same method used to determine initial PBS eligibility; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.</p> <p>An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	Compliance with Authority Required procedures
C14588	P14588	CN14588	Blinatumomab	<p>Acute lymphoblastic leukaemia</p> <p>Induction treatment</p> <p>The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND</p> <p>The condition must not be present in the central nervous system or testis; AND</p> <p>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND</p> <p>Patient must not have received more than 1 line of salvage therapy; AND</p> <p>The condition must be one of the following:</p> <p>(i) untreated with this drug for measurable residual disease, (ii) treated with this drug for measurable residual disease, but the condition has not relapsed within 6 months of completing that course of treatment; AND</p> <p>The condition must have more than 5% blasts in bone marrow; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended.</p> <p>An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and</p> <p>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and</p> <p>(4) if applicable, the date of completion of blinatumomab treatment for measurable residual disease and the date of the patient's subsequent relapse; and</p> <p>(5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14590	P14590	CN14590	Adalimumab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p>	Compliance with Authority Required procedures

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				<p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14591	P14591	CN14591	Certolizumab pegol	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14597	P14597	CN14597	Infliximab	<p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p> <p>Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p>	Compliance with Written Authority Required procedures

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				<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 2 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14600	P14600	CN14600	Etanercept	Severe chronic plaque psoriasis Initial 2 treatment (Whole body) - Change of treatment Must be treated by a dermatologist; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>An adequate response to treatment is defined as</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because</p> <p>(i) there is an absence of an adequate response to that treatment; or</p> <p>(ii) there was an intolerance to that treatment; or</p> <p>(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above.</p> <p>The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</p>	
C14603	P14603	CN14603	Etanercept	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age.</p> <p>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the active joint count, ESR and/or CRP result and date of result;</p> <p>(b) the most recent biological agent and the date of the last continuing prescription.</p> <p>(c) If applicable, the new baseline scores.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14604	P14604	CN14604	Abatacept Golimumab	<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14604

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14608	P14608	CN14608	Budesonide	<p>Eosinophilic oesophagitis</p> <p>Initial treatment - Induction of remission</p> <p>Patient must have a history of symptoms of oesophageal dysfunction; AND</p> <p>Patient must have eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy confirming the presence of at least 15 eosinophils in at least one high power field (hpf); corresponding to approximately 60 eosinophils per mm² hpf; AND</p> <p>Patient must not receive more than 90 days of treatment under this restriction; AND</p> <p>Must be treated by a prescriber who is either:</p> <p>(i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis.</p> <p>Applications for treatment of this condition must be received within 12 weeks of biopsy.</p> <p>Symptoms of oesophageal dysfunction include at least one of the following dysphasia, odynophagia, transient or self-cleared food impaction, chest pain, epigastric discomfort, vomiting/regurgitation.</p> <p>Diagnostic sensitivity increases with the number of biopsies and can be optimised, where necessary, by taking at least eight biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).</p> <p>After prescribing the Initial induction treatment with budesonide, a histologic assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing therapy.</p> <p>The histologic assessment should be conducted no later than 2 weeks prior to completing the PBS-subsidised First continuing maintenance treatment course to avoid an interruption of supply for continuing therapy.</p>	Compliance with Authority Required procedures
C14610	P14610	CN14610	Budesonide	<p>Eosinophilic oesophagitis</p> <p>First continuing treatment - until remission is confirmed</p> <p>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not receive more than 36 weeks of treatment under this restriction; AND Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types. Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction). The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment. The result of the histological assessment must be documented in the patient's medical records. First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.</p>	
C14613	P14613	CN14613	Upadacitinib	<p>Severe active rheumatoid arthritis Continuing treatment - balance of supply Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14615	P14615	CN14615	Infliximab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p> <p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p>	<p>Compliance with Written Authority Required procedures</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14617	P14617	CN14617	Abatacept	<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p> <p>Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of</p>	Compliance with Written Authority Required procedures

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				<p>continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or</p> <p>Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age.</p> <p>If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.</p> <p>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.</p> <p>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.</p> <p>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.</p> <p>Up to a maximum of 4 repeats will be authorised.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14619	P14619	CN14619	Budesonide	<p>Eosinophilic oesophagitis</p> <p>Subsequent continuing treatment - Maintenance of remission</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have documented evidence of having achieved histologic remission while receiving Initial and First continuing PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per mm² hpf on oesophageal biopsy; AND</p> <p>The condition must not have progressed while being treated with this drug; AND</p> <p>Must be treated by a prescriber who is either:</p> <ul style="list-style-type: none"> (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) medical practitioner who has consulted at least one of the above-mentioned prescriber types. <p>Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction).</p> <p>The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14621	P14621	CN14621	Tocilizumab	<p>The result of the histological assessment must be documented in the patient's medical records.</p> <p>First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.</p> <p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14621</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14622	P14622	CN14622	Certolizumab pegol	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction; Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14623	P14623	CN14623	Infliximab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND</p> <p>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND</p> <p>Patient must not receive more than 22 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total</p>	

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				<p>number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.</p>	
C14626	P14626	CN14626	Golimumab	<p>Severe active rheumatoid arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following:</p> <p>(i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or</p> <p>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs</p>	

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				<p>specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.</p> <p>The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application</p> <p>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	

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C14628	P14628	CN14628	Ustekinumab	<p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Severe chronic plaque psoriasis Continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards Must be treated by a dermatologist; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p>	Compliance with Authority Required procedures

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C14629	P14629	CN14629	Etanercept	<p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>The assessment of response to treatment must be provided in this application and documented in the patient's medical records.</p> <p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14629

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C14631	P14631	CN14631	Blinatumomab	<p>joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p> <p>Initial treatment of measurable residual disease of Pre-B-cell ALL</p> <p>Must be treated by a physician experienced in the treatment of haematological malignancies; AND</p> <p>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND</p> <p>The condition must not be present in the central nervous system or testis; AND</p> <p>Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy; AND</p> <p>Patient must have measurable residual disease based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL/as subsequent salvage therapy, whichever was the later, measured using flow cytometry/molecular methods; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle.</p> <p>For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.</p>	Compliance with Written Authority Required procedures

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				<p>An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed Measurable residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and (4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application. <p>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.</p>	
C14632	P14632	CN14632	Teduglutide	<p>Type III Short bowel syndrome with intestinal failure</p> <p>Continuing treatment</p> <p>Must be treated by a gastroenterologist; or</p> <p>Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit; AND</p> <p>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND</p> <p>Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline. or</p> <p>Patient must have, as a patient yet to turn 18 years of age, a reduction in the mean weekly parenteral support volume of at least 20% (mL per kg of body weight) relative to baseline. or</p> <p>The treatment must be resuming after a break in therapy, but before the break in therapy occurred, a reduction in parenteral support relative to baseline had been occurring to an extent as stated as above.</p> <p>Refer to the measurement(s) stated in the Initial treatment authority application for the baseline dependence on parenteral support. Determine the current mean use per week of parental support in days (for a patient of any age) and/or the mean</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>volume per week in mL per kg (for a patient yet to turn 18 years of age). State these values in this authority application.</p> <p>The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.</p> <p>The current mean weekly parenteral support volume is calculated as the mean mL per kg of body weight of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.</p> <p>From 1 September 2021</p> <p>Where the mean weekly volume of parenteral support in terms of mL per kg of body weight for 4 consecutive weeks has not been stated in an Initial treatment authority application for a patient yet to turn 18 years of age, provide in this authority application both</p> <p>(i) a known or estimated retrospective baseline value that would have applied to the patient immediately before commencing treatment with this drug, and</p> <p>(ii) the current value (observed over a 4 week timeframe)</p> <p>Provide these values for a child only where mean weekly volume is to be used as an alternative response assessment to mean days of parenteral support per week. Otherwise, continue to use mean days per week.</p> <p>Where treatment is resuming after a break in treatment with this drug, state parenteral support days/volume values as occurring prior to the break instead of current values.</p> <p>A patient who has turned 18 years of age since their last authority application may be assessed for response using either the mean number of days of parenteral support or mean volume of parenteral support. Any subsequent authority application after this application must be assessed using the mean number of days of parenteral support.</p> <p>Patients who do not meet the clinical criteria with respect to demonstrating the minimum reduction in parenteral support must permanently discontinue PBS subsidy.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p>	

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C14633	P14633	CN14633	Upadacitinib	<p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Severe active rheumatoid arthritis Continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction; Patient must be at least 18 years of age. An adequate response to treatment is defined as an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50% (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p>	
C14636	P14636	CN14636	Ustekinumab	<p>Severe chronic plaque psoriasis</p> <p>Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly</p>	Compliance with Written Authority Required procedures

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				<p>(whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must not receive more than 28 weeks of treatment under this restriction; Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy (a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or (b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled; (iv) the dates that response assessments were determined.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);</p> <p>(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.</p> <p>Provide in this authority application, and document in the patient's medical records, each of</p> <p>(i) the name of each prior therapy trialled that meets the above requirements - state at least 2;</p> <p>(ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies);</p> <p>(iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled;</p> <p>(iv) the dates that response assessments were determined.</p> <p>(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);</p> <p>(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.</p> <p>Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment</p> <p>(v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe);</p> <p>(vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.</p>	
C14638	P14638	CN14638	Infliximab	<p>Severe active rheumatoid arthritis</p> <p>First continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14638</p>

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				<p>Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;</p> <p>Patient must be at least 18 years of age.</p> <p>An adequate response to treatment is defined as</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14643	P14643	CN14643	Ustekinumab	<p>The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.</p> <p>Severe chronic plaque psoriasis</p> <p>Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years</p> <p>Must be treated by a dermatologist; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND</p> <p>The treatment must be as systemic monotherapy; or</p> <p>The treatment must be in combination with methotrexate; AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.</p> <p>Response to preceding supply</p> <p>An adequate response to treatment is defined as</p>	Compliance with Written Authority Required procedures

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.</p> <p>Change in therapy</p> <p>If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because</p> <p>(i) there is an absence of an adequate response to that treatment; or</p> <p>(ii) there was an intolerance to that treatment; or</p> <p>(iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above</p> <p>(i) an absence of an adequate response; or</p> <p>(ii) an intolerance to that treatment; or</p> <p>(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.</p> <p>Recommencing therapy</p> <p>If the patient is recommencing therapy, in relation to the last administered dose, state whether there was</p> <p>(i) an absence of an adequate response; or</p> <p>(ii) an intolerance to that treatment; or</p> <p>(iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above.</p> <p>The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.</p>	
C14647	P14647	CN14647	Tofacitinib	<p>Severe active juvenile idiopathic arthritis</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023; AND</p> <p>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate prior to initiating treatment with this drug for this condition; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens prior to initiating treatment with this drug for this condition:</p> <ul style="list-style-type: none"> (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; <p>AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be under 18 years of age.</p> <p>Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <ul style="list-style-type: none"> (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list <ul style="list-style-type: none"> (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). 	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14649	P14649	CN14649	Tofacitinib	<p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14650	P14650	CN14650	Tofacitinib	<p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must have either:</p> <p>(a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>Active joints are defined as</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.</p> <p>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) the date of the last continuing prescription.</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14652	P14652	CN14652	Tofacitinib	<p>course of PBS-subsidised biological medicine treatment, within the timeframes specified below.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be under 18 years of age. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.</p> <p>Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.</p> <p>If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; OR</p> <p>(b) at least 4 active joints from the following list</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to prior treatment must be documented in the patient's medical records.</p> <p>The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>The following information must be provided by the prescriber at the time of application and documented in the patient's medical records</p> <p>(a) the date of assessment of severe active juvenile idiopathic arthritis; and</p> <p>(b) details of prior treatment including dose and duration of treatment.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14653	P14653	CN14653	Upadacitinib	<p>Severe Crohn disease</p> <p>Balance of supply for Initial (induction) treatment phases</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions; AND</p> <p>The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.</p>	Compliance with Authority Required procedures
C14655	P14655	CN14655	Adalimumab Etanercept Golimumab Ixekizumab Secukinumab Tofacitinib Upadacitinib	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p>	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14656	P14656	CN14656	Adalimumab Etanercept	<p>Ankylosing spondylitis</p> <p>Subsequent continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p>	Compliance with Written Authority Required procedures

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				<p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14659	P14659	CN14659	Certolizumab pegol	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND</p> <p>Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and</p> <p>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a baseline BASDAI score; and</p> <p>(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and</p> <p>(iv) baseline ESR and/or CRP level.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14662	P14662	CN14662	<p>Adalimumab</p> <p>Etanercept</p> <p>Golimumab</p> <p>Ixekizumab</p> <p>Secukinumab</p> <p>Tofacitinib</p> <p>Upadacitinib</p>	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be either radiologically (plain X-ray) confirmed:</p> <p>(i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND</p> <p>Patient must have at least 2 of the following:</p> <p>(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND</p> <p>Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a baseline BASDAI score; and</p> <p>(iii) a baseline ESR and/or CRP level.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14667	P14667	CN14667	Infliximab	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND</p> <p>Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND</p> <p>Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not receive more than 18 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The following must be provided at the time of application and documented in the patient's medical records (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Up to a maximum of 3 repeats will be authorised. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	

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C14668	P14668	CN14668	Infliximab	<p>Ankylosing spondylitis</p> <p>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>The treatment must have both:</p> <p>(i) provided the patient with an adequate response with the preceding supply, (ii) been assessed for response after at least 12 weeks of therapy; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>All measurements provided must be no more than 1 month old at the time of application.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14670	P14670	CN14670	Adalimumab Etanercept Golimumab Ixekizumab Secukinumab Tofacitinib Upadacitinib	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND</p> <p>Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application</p>	Compliance with Written Authority Required procedures

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				<p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and</p> <p>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a baseline BASDAI score; and</p> <p>(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and</p> <p>(iv) baseline ESR and/or CRP level.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14671	P14671	CN14671	Etanercept	<p>in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND</p> <p>Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND</p> <p>Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p>	Compliance with Authority Required procedures

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				<p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a baseline BASDAI score; and</p> <p>(iii) a baseline ESR and/or CRP level.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14672	P14672	CN14672	Adalimumab	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>The condition must be either radiologically (plain X-ray) confirmed:</p> <p>(i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND</p> <p>Patient must have at least 2 of the following:</p> <p>(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND</p> <p>Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a baseline BASDAI score; and</p> <p>(iii) a baseline ESR and/or CRP level.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p>	

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C14673	P14673	CN14673	Adalimumab Etanercept	<p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14676	P14676	CN14676	Nivolumab	<p>Advanced or metastatic gastro-oesophageal cancers</p> <p>Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND</p> <p>Patient must be untreated (up until initiating this drug) with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer; AND</p> <p>Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first:</p> <p>(i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs;</p> <p>Patient must be in one of the three population subsets described below.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14676</p>

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				<p>Population 1 Conditions gastric cancer, gastro-oesophageal junction cancer, oesophageal adenocarcinoma Concomitant therapies chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment first-line drug treatment Additional clinical finding HER2 negative</p> <p>Population 2 Condition oesophageal squamous cell carcinoma (can be recurrent) Concomitant therapies chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment first-line drug treatment Additional clinical finding unresectable</p> <p>Population 3 Condition oesophageal squamous cell carcinoma (can be recurrent) Line of treatment second-line drug treatment after chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Additional clinical finding unresectable</p>	
C14683	P14683	CN14683	Adalimumab Etanercept Infliximab	<p>Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following (a) an ESR measurement no greater than 25 mm per hour; or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14683

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14686	P14686	CN14686	Certolizumab pegol	<p>(b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a baseline BASDAI score; and</p> <p>(iii) a baseline ESR and/or CRP level.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14689	P14689	CN14689	Infliximab	<p>Ankylosing spondylitis</p> <p>First continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14689</p>

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				<p>condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14692	P14692	CN14692	Certolizumab pegol Golimumab Ixekizumab Secukinumab Tofacitinib Upadacitinib	<p>Ankylosing spondylitis</p> <p>Continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14696	P14696	CN14696	Upadacitinib	<p>Severe Crohn disease</p> <p>Transitioning from non-PBS to PBS-subsidised supply - 'grandfather' arrangements</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023; AND</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; or</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; or</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND</p> <p>Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; or</p> <p>Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; or</p> <p>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; AND</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following</p> <p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14697	P14697	CN14697	Tofacitinib	<p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>Evidence of intestinal inflammation includes</p> <p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>All assessments, pathology tests and diagnostic imaging studies were to have been within 4 weeks leading up to commencing the non-PBS subsidised supply of this drug and should have been performed preferably whilst still on conventional treatment, but no longer than 4 weeks following the last dose of conventional treatment.</p> <p>Where extensive small intestinal disease affecting more than 50 cm of the small intestine applies, the CDAI must have been at least 220 prior to commencing the non-PBS subsidised supply of this drug.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p>	Compliance with Authority Required

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				<p>Must be treated by a rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>An adequate response to treatment is defined as</p> <p>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.</p> <p>The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	<p>procedures - Streamlined Authority Code 14697</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.</p>	
C14698	P14698	CN14698	Upadacitinib	<p>Severe Crohn disease</p> <p>Balance of supply for the Continuing (maintenance) treatment phase</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>The treatment must have been prescribed in a quantity in the most recent prescription which did not seek the full quantity available in regards to any of: (i) the quantity per dispensing, (ii) repeat prescriptions; AND</p> <p>The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under.</p>	Compliance with Authority Required procedures
C14701	P14701	CN14701	Adalimumab Etanercept Infliximab	<p>Ankylosing spondylitis</p> <p>Subsequent continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14701

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				<p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14703	P14703	CN14703	Etanercept	<p>Ankylosing spondylitis</p> <p>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must provide no more than the balance of up to 16 weeks treatment; AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	
C14705	P14705	CN14705	Infliximab	Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment; AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
C14707	P14707	CN14707	Infliximab	Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 18 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.	Compliance with Authority Required procedures

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				<p>Up to a maximum of 3 repeats will be authorised.</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <ul style="list-style-type: none">(a) an ESR measurement no greater than 25 mm per hour; or(b) a CRP measurement no greater than 10 mg per L; or(c) an ESR or CRP measurement reduced by at least 20% from baseline. <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C14708	P14708	CN14708	Durvalumab	<p>Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer)</p> <p>Patient must have either of the following at treatment initiation:</p> <p>(i) locally advanced biliary tract cancer that is untreated with systemic anti-cancer therapy in the unresectable setting, (ii) metastatic biliary tract cancer that is untreated with systemic anti-cancer therapy in the metastatic setting;</p> <p>Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug; AND</p> <p>The treatment must be/have been initiated with both:</p> <p>(i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information); AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14708
C14709	P14709	CN14709	Upadacitinib	<p>Severe Crohn disease</p> <p>Continuing (maintenance) treatment</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or</p> <p>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:</p> <p>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin</p>	Compliance with Written Authority Required procedures

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C14710	P14710	CN14710	Upadacitinib	<p>level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not more than 4 weeks from the last administered dose</p> <p>(i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or</p> <p>(ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant.</p> <p>Severe Crohn disease</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; or</p> <p>Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; or</p> <p>Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND</p> <p>Patient must have evidence of intestinal inflammation; or</p> <p>Patient must be assessed clinically as being in a high faecal output state; or</p> <p>Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Provide at least one of the following</p> <p>(i) the current Crohn Disease Activity Index (CDAI) score, including the date this score was calculated on;</p> <p>(ii) confirmation that there is a documented history of intestinal inflammation plus diagnostic imaging/surgical evidence of at least one of (a) short gut syndrome, (b) ileostomy, (c) colostomy;</p> <p>(iii) confirmation that there is a documented history and radiological evidence of intestinal inflammation from extensive small intestinal disease affecting more than 50 cm of the small intestine where the CDAI score is at least 220, but below 300.</p> <p>Evidence of intestinal inflammation includes</p> <p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p>	

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				<p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p>	
C14711	P14711	CN14711	Upadacitinib	<p>Severe Crohn disease</p> <p>Extended induction period (optional) from weeks 12 to 24</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have experienced an inadequate therapeutic benefit following at least one of:</p> <p>(i) dosing with 45 mg daily in the initial 12-week induction period, (ii) dosing with 15 mg daily;</p> <p>Patient must be at least 18 years of age.</p>	Compliance with Authority Required procedures
C14713	P14713	CN14713	Adalimumab Etanercept	<p>Ankylosing spondylitis</p> <p>First continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <ul style="list-style-type: none"> (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	

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C14714	P14714	CN14714	Certolizumab pegol	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14715	P14715	CN14715	Etanercept	<p>Ankylosing spondylitis</p> <p>Continuing treatment - balance of supply</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p>	Compliance with Authority Required procedures

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C14716	P14716	CN14716	Infliximab	<p>Ankylosing spondylitis</p> <p>First continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14718	P14718	CN14718	Infliximab	<p>will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 18 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Details of the NSAIDs trialed, their doses and duration of treatment must be provided at the time of application.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.</p> <p>All relevant details must be documented in the patient's medical records.</p> <p>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and</p> <p>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.</p> <p>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.</p> <p>The following must be provided at the time of application</p> <p>(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</p> <p>(ii) a baseline BASDAI score; and</p> <p>(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and</p> <p>(iv) baseline ESR and/or CRP level.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p>	
C14720	P14720	CN14720	Tofacitinib	<p>Ankylosing spondylitis</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND</p> <p>Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND</p>	Compliance with Written Authority Required procedures

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				<p>Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months prior to commencing non-PBS-subsidised treatment; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p> <p>The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and</p> <p>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <ul style="list-style-type: none"> (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <ul style="list-style-type: none"> (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this</p>	

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				condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C14721	P14721	CN14721	Upadacitinib	<p>Severe Crohn disease</p> <p>Initial 1 (induction treatment covering the first 12 weeks in a patient untreated with biological medicine)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];</p> <p>Patient must be at least 18 years of age;</p> <p>Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; or</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; or</p> <p>Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND</p> <p>Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy. or</p> <p>Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. or</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following</p> <p>(a) patient must have evidence of intestinal inflammation;</p> <p>(b) patient must be assessed clinically as being in a high faecal output state;</p> <p>(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.</p> <p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>Evidence of intestinal inflammation includes</p> <p>(i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or</p> <p>(ii) faeces higher than normal lactoferrin or calprotectin level; or</p> <p>(iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.</p> <p>All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst</p>	

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				<p>still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.</p> <p>If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.</p> <p>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.</p> <p>Details of the accepted toxicities including severity can be found on the Services Australia website.</p> <p>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.</p>	
C14723	P14723	CN14723	Infliximab	<p>Ankylosing spondylitis</p> <p>Subsequent continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or</p> <p>Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14723

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				<p>(c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14724	P14724	CN14724	Infliximab	<p>Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction; Patient must be at least 18 years of age; Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include (1) a completed authority prescription form; and</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <p>(a) an ESR measurement no greater than 25 mm per hour; or</p> <p>(b) a CRP measurement no greater than 10 mg per L; or</p> <p>(c) an ESR or CRP measurement reduced by at least 20% from baseline.</p> <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	

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C14726	P14726	CN14726	Bimekizumab	<p>Severe chronic plaque psoriasis</p> <p>Grandfathered patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)</p> <p>Patient must have a documented severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where lesions have been present for at least 6 months prior to commencing non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2023; AND</p> <p>Patient must have a documented failure to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 5 treatments prior to commencing non-PBS-subsidised treatment with this drug for this condition:</p> <p>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; AND</p> <p>Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <p>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and</p> <p>(c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</p> <p>The most recent PASI assessment must be no more than 4 weeks old at the time of application.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p>	
C14727	P14727	CN14727	Pembrolizumab	<p>Stage II or Stage III triple negative breast cancer</p> <p>The treatment must be initiated in combination with neoadjuvant chemotherapy;</p> <p>AND</p> <p>The condition must not have progressed/recurred whilst on treatment with this drug;</p> <p>AND</p> <p>Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction; AND</p> <p>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions. or</p> <p>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 4 repeat prescriptions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14727
C14728	P14728	CN14728	Upadacitinib	<p>Severe Crohn disease</p> <p>Continuing (maintenance) treatment</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or</p> <p>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:</p> <ul style="list-style-type: none"> (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; or <p>The condition must have not met the improvements specified above due to the prescribed dose being too low - this authority application seeks higher dosing;</p> <p>Patient must be at least 18 years of age.</p> <p>The authority application must be made in writing and must include</p> <ul style="list-style-type: none"> (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>In relation to the immediately preceding supply of this biological medicine, provide at least one of the following which is not more than 4 weeks from the last administered dose</p> <ul style="list-style-type: none"> (i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or (ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant. 	
C14729	P14729	CN14729	Zoledronic acid	<p>Adjuvant management of breast cancer</p> <p>Patient must be post-menopausal;</p>	<p>Compliance with Authority Required</p>

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				Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.	procedures - Streamlined Authority Code 14729
C14730	P14730	CN14730	Adalimumab	Ankylosing spondylitis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Authority Required procedures
C14734	P14734	CN14734	Upadacitinib	Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND The treatment must not have on a previous occasion failed to provide the patient with an adequate response during the current treatment cycle; Patient must be at least 18 years of age. The authority application must be made in writing and must include (1) a completed authority prescription form; and	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>In relation to the biological medicine prescribed immediately before this one, provide at least one of the following which is not more than 4 weeks from the last administered dose</p> <p>(i) the Crohn Disease Activity Index (CDAI) score, including the date the score was calculated on; or</p> <p>(ii) the unique serial/identifying number and date(s) of pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; or</p> <p>(iii) confirmation that a severe intolerance occurred that resulted in the cessation of treatment.</p>	
C14735	P14735	CN14735	Zoledronic acid	<p>Adjuvant management of breast cancer</p> <p>Patient must be post-menopausal;</p> <p>Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14735</p>
C14737	P14737	CN14737	Infliximab	<p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND</p> <p>Patient must not receive more than 18 weeks of treatment under this restriction;</p> <p>Patient must be at least 18 years of age;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form; and</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.</p> <p>Up to a maximum of 3 repeats will be authorised.</p> <p>An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.</p> <p>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following</p> <ul style="list-style-type: none">(a) an ESR measurement no greater than 25 mm per hour; or(b) a CRP measurement no greater than 10 mg per L; or(c) an ESR or CRP measurement reduced by at least 20% from baseline. <p>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.</p> <p>The assessment of response to treatment must be documented in the patient's medical records.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.</p> <p>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>	
C14741	P14741	CN14741	Olaparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial first-line maintenance therapy (BRCA1/2 gene mutation)</p> <p>The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test; AND</p> <p>Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug class for the first time. or</p> <p>Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p> <p>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.</p>	Compliance with Authority Required procedures
C14742	P14742	CN14742	Olaparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation)</p>	Compliance with Authority Required procedures

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				<p>Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.</p>	
C14744	P14744	CN14744	Ravulizumab	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Switch from PBS-subsidised eculizumab (all phases) - loading dose</p> <p>Patient must have previously received PBS-subsidised eculizumab under the 'Initial treatment' restriction for this condition; or</p> <p>Patient must have previously received PBS-subsidised eculizumab under the 'Continuing treatment' restriction for this condition; or</p> <p>Patient must have previously received PBS-subsidised eculizumab under the 'Extended continuing treatment' restriction for this condition; or</p> <p>Patient must have previously received PBS-subsidised eculizumab under the 'Recommendation of treatment' restriction for this condition; or</p> <p>Patient must have previously received PBS-subsidised eculizumab under the 'Continuing recommendation of treatment' restriction for this condition; AND</p> <p>Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND</p> <p>Patient must not receive more than 2 weeks of treatment under this restriction; AND</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>The application must indicate the most recent treatment phase that the patient is switching from.</p>	Compliance with Authority Required procedures

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C14746	P14746	CN14746	Ravulizumab	<p>For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.</p> <p>Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>The authority application must be in writing and must include all of the following</p> <ul style="list-style-type: none"> (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted. <p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements</p> <p>Patient must have previously received non-PBS-subsidised therapy with this drug for this condition; AND</p> <p>Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS supply was commenced, the patient:</p> <ul style="list-style-type: none"> (i) had active and progressing thrombotic microangiopathy (TMA) caused by aHUS; (ii) had ADAMTS-13 activity of greater than or equal to 10% on a blood sample not confounded by any plasma exchange or infusion; (iii) had a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days of commencing ravulizumab treatment; (iv) had clinical features of active organ damage or impairment; AND <p>Patient must have demonstrated ongoing treatment response with ravulizumab for this condition if received at least 26 weeks of initial non-PBS-subsidised therapy; AND</p> <p>Patient must not have experienced treatment failure with ravulizumab for this condition if they have received at least 26 weeks of initial non-PBS-subsidised therapy; AND</p> <p>Must be treated by a prescriber who is either:</p> <ul style="list-style-type: none"> (i) a haematologist, (ii) a nephrologist; or 	Compliance with Authority Required procedures

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				<p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>Evidence of active and progressing TMA is defined by the following</p> <p>(1) A platelet count of less than $150 \times 10^9/L$; and evidence of at least two of the following</p> <ul style="list-style-type: none"> (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; or <p>(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and</p> <p>(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below</p> <ul style="list-style-type: none"> (a) kidney impairment as demonstrated by one or more of the following <ul style="list-style-type: none"> (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; (iv) a renal biopsy consistent with aHUS; (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment. <p>Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.</p> <p>The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such</p>	

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				<p>as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.</p> <p>Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A detailed cover letter from the prescriber;</p> <p>(4) A measurement of body weight at the time of application;</p> <p>(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay;</p> <p>(6) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days of initiating treatment with non-PBS-subsidised ravulizumab;</p> <p>(7) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of commencement of non-PBS-subsidised ravulizumab;</p> <p>(8) For patients who have received at least 26 weeks of ravulizumab treatment, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.</p>	
C14747	P14747	CN14747	Ravulizumab	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Extended continuing treatment</p> <p>Patient must have received PBS-subsidised ravulizumab under the continuing treatment phase for this condition; or</p> <p>Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; or</p> <p>Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the extended continuing treatment phase for this condition; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition; AND</p> <p>Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase; AND</p> <p>Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; or</p> <p>Patient must have severe TMA-related neurological impairment; or</p> <p>Patient must have severe TMA-related gastrointestinal impairment; or</p> <p>Patient must have severe TMA-related pulmonary impairment on current objective measurement; or</p> <p>Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); or</p> <p>Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with ravulizumab; AND</p> <p>Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction; AND</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>A treatment response is defined as</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and</p> <p>(2) One of the following</p> <p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p>	

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				<p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is</p> <ol style="list-style-type: none"> (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented. <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following</p> <ol style="list-style-type: none"> (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted; (5) A family history of aHUS, if applicable; (6) A history of multiple episodes of aHUS before commencing ravulizumab treatment, if applicable; (7) A history of kidney transplant, if applicable (especially if required due to aHUS); (8) An inclusion of the individual consequences of recurrent disease; (9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; (10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application; 	

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C14748	P14748	CN14748	Ravulizumab	<p>(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;</p> <p>(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.</p> <p>Atypical haemolytic uraemic syndrome (aHUS) Balance of Supply - maintenance doses Patient must have received PBS-subsidised loading dose of ravulizumab for this condition for this current treatment phase; AND Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND Patient must have received insufficient therapy to complete the maximum allowable treatment under their specified treatment phase; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the relevant treatment phase; AND Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14749	P14749	CN14749	Ravulizumab	<p>infusion and must have been submitted to Services Australia within 13 days of commencement of ravulizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia.</p> <p>Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Continuing treatment</p> <p>Patient must have received PBS-subsidised ravulizumab under the initial treatment phase for this condition; or</p> <p>Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; or</p> <p>Patient must have received PBS-subsidised ravulizumab under the grandfather restriction for this condition; AND</p> <p>Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition; AND</p> <p>Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase; AND</p> <p>Patient must not receive more than 72 weeks of ravulizumab treatment in total under this restriction; or</p> <p>Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment; AND</p> <p>Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction; AND</p> <p>Must be treated by a prescriber who is either:</p> <p>(i) a haematologist, (ii) a nephrologist; or</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p>	Compliance with Authority Required procedures

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				<p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>A treatment response is defined as</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and</p> <p>(2) One of the following</p> <p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS, if applicable;</p> <p>(6) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(7) An inclusion of the individual consequences of recurrent disease, if applicable;</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;</p> <p>(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;</p> <p>(10) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.</p>	
C14750	P14750	CN14750	Eculizumab	<p>Atypical haemolytic uraemic syndrome (aHUS) Recommencement - Balance of Supply Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition; AND Patient must not receive more than 20 weeks supply under this restriction; AND Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p>	Compliance with Authority Required procedures
C14753	P14753	CN14753	Eculizumab	<p>Atypical haemolytic uraemic syndrome (aHUS) Switch from PBS-subsidised ravulizumab (all phases) - loading dose Patient must have previously received PBS-subsidised ravulizumab under the 'Initial treatment' restriction for this condition; or</p>	Compliance with Authority Required procedures

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				<p>Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing treatment' restriction for this condition; or</p> <p>Patient must have previously received PBS-subsidised ravulizumab under the 'Extended continuing treatment' restriction for this condition; or</p> <p>Patient must have previously received PBS-subsidised ravulizumab under the 'Recommendment of treatment' restriction for this condition; or</p> <p>Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing recommencement of treatment' restriction for this condition; or</p> <p>Patient must have previously received PBS-subsidised ravulizumab under the 'Grandfather (transitioning from non-PBS to PBS-subsidised treatment)' restriction for this condition; AND</p> <p>Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND</p> <p>Patient must not receive more than 24 weeks of C5 inhibitor supply for this current treatment phase under this restriction; AND</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>The application must indicate the most recent treatment phase that the patient is switching from.</p> <p>For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.</p> <p>Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14754	P14754	CN14754	Eculizumab	<p>(3) A measurement of body weight at the time of application; (4) Results of genetic testing, if not previously submitted.</p> <p>Atypical haemolytic uraemic syndrome (aHUS) Continuing treatment Patient must have received PBS-subsidised eculizumab under the initial treatment phase for this condition; or Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the initial treatment phase for this condition; or Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; AND Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must not receive more than 80 weeks of eculizumab treatment in total under this restriction; or Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction; AND Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as (1) Normalisation of haematology as demonstrated by at least 2 of the following (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following</p>	Compliance with Authority Required procedures

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				<p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS, if applicable;</p> <p>(6) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(7) An inclusion of the individual consequences of recurrent disease, if applicable;</p> <p>(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;</p> <p>(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis,</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14757	P14757	CN14757	Lumacaftor with ivacaftor	<p>unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;</p> <p>(10) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.</p> <p>Cystic fibrosis Continuing treatment Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND The treatment must be given concomitantly with standard therapy for this condition; Patient must be 1 year of age or older. This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information. The authority application must be in writing and must include (1) a completed authority prescription; and (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	Compliance with Authority Required procedures

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C14758	P14758	CN14758	Ustekinumab	<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle; AND</p> <p>Must be treated by a gastroenterologist (code 87). or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>Applications for authorisation must be made in writing and must include</p> <p>(1) two completed authority prescription forms; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following</p> <p>(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior biological medicine treatment including details of date and duration of treatment.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.</p> <p>The most recent fistula assessment must be no more than 4 weeks old at the time of application.</p> <p>A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised</p> <p>Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.</p> <p>Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p>	
C14760	P14760	CN14760	Olaparib	<p>High grade epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Continuation of subsequent-line maintenance therapy (BRCA1/2 gene mutation)</p> <p>The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase:</p> <p>Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14760
C14761	P14761	CN14761	Olaparib	<p>High grade epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation)</p> <p>The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test; AND</p> <p>The condition must be platinum sensitive; AND</p> <p>Patient must have received at least two previous platinum-containing regimens; AND</p> <p>Patient must have relapsed following a previous platinum-containing regimen; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition.</p> <p>Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p> <p>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.</p>	
C14764	P14764	CN14764	Obinutuzumab	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</p> <p>For combination use with acalabrutinib from treatment cycles 2 to 7 inclusive in first-line therapy</p> <p>The condition must be untreated; AND</p> <p>The treatment must be in combination with PBS-subsidised acalabrutinib (refer to Product Information for timing of obinutuzumab and acalabrutinib doses).</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14764</p>
C14765	P14765	CN14765	Lumacaftor with ivacaftor	<p>Cystic fibrosis</p> <p>Initial treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition;</p> <p>Patient must be 1 year of age or older.</p>	<p>Compliance with Authority Required procedures</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
C14770	P14770	CN14770	Pembrolizumab	<p>Stage IIIB, Stage IIIC or Stage IIID malignant melanoma</p> <p>Initial treatment - 3 weekly treatment regimen</p> <p>The treatment must be in addition to complete surgical resection; AND</p> <p>Patient must have a WHO performance status of 1 or less; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have received prior PBS-subsidised treatment for this condition; AND</p> <p>The treatment must commence within 12 weeks of complete resection; AND</p> <p>Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).</p>	Compliance with Authority Required procedures
C14776	P14776	CN14776	Venetoclax	<p>Chronic lymphocytic leukaemia (CLL)</p> <p>Dose titration for relapsed/refractory disease</p> <p>The condition must have relapsed or be refractory to at least one prior therapy; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND</p> <p>Patient must not be undergoing retreatment with this drug where any of:</p> <p>(i) prior treatment of CLL/SLL with this same drug was unable to prevent disease</p>	Compliance with Authority Required procedures

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				progression; (ii) 24 months of PBS-subsidised treatment has been administered with this drug for this condition.	
C14778	P14778	CN14778	Olaparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation); AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.</p>	Compliance with Authority Required procedures
C14780	P14780	CN14780	Ravulizumab	<p>Atypical haemolytic uraemic syndrome (aHUS) Initial treatment - Initial (new patient) loading dose Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS; AND Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than $150 \mu\text{mol/L}$; AND Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days; AND Patient must have clinical features of active organ damage or impairment; AND Patient must not receive more than 2 weeks of treatment under this restriction; AND Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Evidence of active and progressing TMA is defined by the following</p> <p>(1) A platelet count of less than $150 \times 10^9/L$; and evidence of at least two of the following</p> <ul style="list-style-type: none"> (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; or <p>(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and</p> <p>(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below</p> <ul style="list-style-type: none"> (a) kidney impairment as demonstrated by one or more of the following <ul style="list-style-type: none"> (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; (iv) a renal biopsy consistent with aHUS; (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment. <p>Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.</p> <p>The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.</p> <p>Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p>	

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				<p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A detailed cover letter from the prescriber;</p> <p>(4) A measurement of body weight at the time of application;</p> <p>(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;</p> <p>(6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 13 days of commencement of ravulizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised C5 inhibitor treatment, under Initial balance of supply;</p> <p>(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;</p> <p>(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;</p> <p>(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.</p> <p>Two authority prescription forms will be required to cover for the 26 weeks of initial therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.</p>	
C14781	P14781	CN14781	Eculizumab	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Initial treatment</p> <p>Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS; AND</p> <p>Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than $30 \times 10^9/L$ and a serum creatinine of greater than $150 \mu\text{mol/L}$; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days; AND</p> <p>Patient must have clinical features of active organ damage or impairment; AND</p> <p>Patient must not receive more than 4 weeks of treatment under this restriction; AND</p> <p>Must be treated by a prescriber who is either:</p> <ul style="list-style-type: none"> (i) a haematologist, (ii) a nephrologist; or <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>Evidence of active and progressing TMA is defined by the following</p> <ul style="list-style-type: none"> (1) a platelet count of less than $150 \times 10^9/L$; and evidence of two of the following <ul style="list-style-type: none"> (i) presence of schistocytes on blood film; (ii) low or absent haptoglobin; (iii) lactate dehydrogenase (LDH) above normal range; (2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below <ul style="list-style-type: none"> (a) kidney impairment as demonstrated by one of the following <ul style="list-style-type: none"> (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or (iv) a renal biopsy consistent with aHUS; (b) onset of TMA-related neurological impairment; (c) onset of TMA-related cardiac impairment; (d) onset of TMA-related gastrointestinal impairment; (e) onset of TMA-related pulmonary impairment. <p>OR</p>	

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				<p>(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA;</p> <p>(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below</p> <p>(a) kidney impairment as demonstrated by one of the following</p> <p>(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or</p> <p>(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or</p> <p>(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or</p> <p>(iv) a renal biopsy consistent with aHUS;</p> <p>(b) onset of TMA-related neurological impairment;</p> <p>(c) onset of TMA-related cardiac impairment;</p> <p>(d) onset of TMA-related gastrointestinal impairment;</p> <p>(e) onset of TMA-related pulmonary impairment.</p> <p>AND</p> <p>(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below</p> <p>(a) kidney impairment as demonstrated by one of the following</p> <p>(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or</p> <p>(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or</p> <p>(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or</p> <p>(iv) a renal biopsy consistent with aHUS;</p> <p>(b) onset of TMA-related neurological impairment;</p> <p>(c) onset of TMA-related cardiac impairment;</p> <p>(d) onset of TMA-related gastrointestinal impairment;</p> <p>(e) onset of TMA-related pulmonary impairment.</p> <p>Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.</p> <p>Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>The authority application must be in writing and must include all of the following</p> <ol style="list-style-type: none"> (1) A completed authority prescription form(s); (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice); (3) A detailed cover letter from the prescriber; (4) A measurement of body weight at the time of application; (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay; (6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - Balance of Supply; (7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; (8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application; (9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application. 	
C14783	P14783	CN14783	Lumacaftor with ivacaftor	Cystic fibrosis Initial treatment	Compliance with Authority Required procedures

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C14784	P14784	CN14784	Lumacaftor with ivacaftor	<p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition;</p> <p>Patient must be aged between 6 and 11 years inclusive.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p> <p>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>Patient must be aged between 6 and 11 years inclusive.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	
C14785	P14785	CN14785	Lumacaftor with ivacaftor	<p>Cystic fibrosis</p> <p>Continuing treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition;</p> <p>Patient must be 12 years of age or older.</p>	Compliance with Authority Required procedures

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C14786	P14786	CN14786	Pembrolizumab	<p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and</p> <p>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p>	Compliance with Authority Required procedures
C14787	P14787	CN14787	Ustekinumab	<p>Complex refractory Fistulising Crohn disease</p> <p>Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND</p> <p>Patient must have an externally draining enterocutaneous or rectovaginal fistula; AND</p> <p>Must be treated by a gastroenterologist (code 87). or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Applications for authorisation must be made in writing and must include</p> <p>(1) two completed authority prescription forms; and</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14788	P14788	CN14788	Acalabrutinib Ibrutinib Zanubrutinib	<p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.</p> <p>Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.</p> <p>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised</p> <p>Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.</p> <p>Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.</p> <p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Treatment of relapsed/refractory disease</p> <p>The condition must have relapsed or be refractory to at least one prior therapy; AND</p> <p>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must not be undergoing retreatment (second/subsequent treatment course) with this drug where prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND</p> <p>Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment). or</p> <p>Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent.</p>	
C14791	P14791	CN14791	Ravulizumab	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Recommencement of treatment</p> <p>Patient must have demonstrated treatment response to previous treatment with a PBS-subsidised C5 inhibitor for this condition; AND</p> <p>Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase; AND</p> <p>Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment:</p> <p>(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count $<150 \times 10^9/L$); OR (iii) TMA-related organ impairment including on recent biopsy; AND</p> <p>Must be treated by a prescriber who is either:</p> <p>(i) a haematologist, (ii) a nephrologist; or</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.</p> <p>A treatment response is defined as</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and</p> <p>(2) One of the following</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS if applicable;</p> <p>(6) A history of multiple episodes of aHUS following the treatment break, if applicable;</p> <p>(7) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(8) An inclusion of the individual consequences of recurrent disease;</p> <p>(9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;</p>	

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				<p>(10) Evidence that the patient has had a treatment response to their previous treatment with a C5 inhibitor;</p> <p>(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;</p> <p>(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>Two authority prescription forms will be required to cover for the 26 weeks of recommencement therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.</p>	
C14792	P14792	CN14792	Eculizumab	<p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Initial treatment - Balance of Supply</p> <p>Patient must have received PBS-subsidised initial supply of eculizumab for this condition; AND</p> <p>Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND</p> <p>Patient must not receive more than 20 weeks supply under this restriction; AND</p> <p>Must be treated by a prescriber who is either:</p> <p>(i) a haematologist, (ii) a nephrologist; or</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion, and must have been submitted to Services Australia within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14793	P14793	CN14793	Eculizumab	<p>or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.</p> <p>Atypical haemolytic uraemic syndrome (aHUS) Continuing recommencement of treatment Patient must have received PBS-subsidised eculizumab under the recommencement of treatment phase for this condition; or Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; or Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing recommencement of treatment phase for this condition; AND Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must not receive more than 24 weeks of treatment with eculizumab per continuing treatment course authorised under this restriction; AND Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. A treatment response is defined as (1) Normalisation of haematology as demonstrated by at least 2 of the following (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or b) an eGFR within +/- 25% from baseline; or</p>	Compliance with Authority Required procedures

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				<p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS, if applicable;</p> <p>(6) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable;</p> <p>(7) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(8) An inclusion of the individual consequences of recurrent disease, if applicable;</p> <p>(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;</p> <p>(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis,</p>	

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				<p>unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;</p> <p>(11) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.</p>	
C14796	P14796	CN14796	Lumacaftor with ivacaftor	<p>Cystic fibrosis</p> <p>Initial treatment</p> <p>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND</p> <p>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND</p> <p>The treatment must be given concomitantly with standard therapy for this condition; AND</p> <p>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND</p> <p>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition;</p> <p>Patient must be 12 years of age or older.</p> <p>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.</p> <p>The authority application must be in writing and must include</p> <p>(1) a completed authority prescription; and</p> <p>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and</p>	Compliance with Authority Required procedures

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C14797	P14797	CN14797	Ravulizumab	<p>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and</p> <p>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.</p> <p>Atypical haemolytic uraemic syndrome (aHUS) Continuing recommencement of treatment Patient must have received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; or Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Recommencement treatment' restriction for this condition; or Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Continuing recommencement treatment' restriction for this condition; AND Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition; AND Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase; AND Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction; AND Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. A treatment response is defined as (1) Normalisation of haematology as demonstrated by at least 2 of the following (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and (2) One of the following</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS, if applicable;</p> <p>(6) A history of multiple episodes of aHUS before recommencing ravulizumab treatment, if applicable;</p> <p>(7) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(8) An inclusion of the individual consequences of recurrent disease, if applicable;</p> <p>(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;</p>	

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C14799	P14799	CN14799	Eculizumab	<p>(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;</p> <p>(11) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.</p> <p>Atypical haemolytic uraemic syndrome (aHUS) Recommencement of treatment Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition; or Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; AND Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10⁹/L); OR (iii) TMA-related organ impairment including on recent biopsy; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>A treatment response is defined as</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and</p> <p>(2) One of the following</p> <p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p> <p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS if applicable;</p> <p>(6) A history of multiple episodes of aHUS following the treatment break, if applicable;</p>	

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				<p>(7) A history of kidney transplant if applicable (especially if required due to aHUS);</p> <p>(8) An inclusion of the individual consequences of recurrent disease;</p> <p>(9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;</p> <p>(10) Evidence that the patient has had a treatment response to their previous treatment with eculizumab;</p> <p>(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;</p> <p>(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p>	
C14801	P14801	CN14801	Ustekinumab	<p>Complex refractory Fistulising Crohn disease</p> <p>Initial 1 (new patient or commencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or commencement of treatment after a break in biological medicine of less than 5 years) - balance of supply</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or commencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND</p> <p>Must be treated by a gastroenterologist (code 87). or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14802	P14802	CN14802	Ustekinumab	<p>Complex refractory Fistulising Crohn disease Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have had prior to commencing non-PBS-subsidised treatment: (1) confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; (2) an externally draining enterocutaneous or rectovaginal fistula; AND Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2024; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition if received at least 12 weeks of initial non-PBS-subsidised therapy; AND Must be treated by a gastroenterologist (code 87). or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes (i) the completed baseline Fistula Assessment Form prior to initiating treatment including the date of assessment; (ii) the completed current Fistula Assessment Form including the date of assessment demonstrating the patient's adequate response to treatment if the patient has received at least 12 weeks of treatment. An adequate response is defined as (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or</p>	Compliance with Authority Required procedures

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C14805	P14805	CN14805	Eculizumab	<p>(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. No repeats will be authorised for patients transitioning from non-PBS-subsidised to PBS-subsidised treatment who have only received the first infusion of ustekinumab.</p> <p>The most recent fistula assessment must be no more than 1 month old at the time of application.</p> <p>Atypical haemolytic uraemic syndrome (aHUS)</p> <p>Extended Continuing treatment</p> <p>Patient must have received PBS-subsidised eculizumab under the continuing treatment phase for this condition; or</p> <p>Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; or</p> <p>Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the extended continuing treatment phase for this condition; AND</p> <p>Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition; AND</p> <p>Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase; AND</p> <p>Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; or</p> <p>Patient must have severe TMA-related neurological impairment; or</p> <p>Patient must have severe TMA-related gastrointestinal impairment; or</p> <p>Patient must have severe TMA-related pulmonary impairment on current objective measurement; or</p> <p>Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); or</p> <p>Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab; AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction; AND</p> <p>Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; or</p> <p>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.</p> <p>A treatment response is defined as</p> <p>(1) Normalisation of haematology as demonstrated by at least 2 of the following (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and</p> <p>(2) One of the following</p> <p>a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or</p> <p>b) an eGFR within +/- 25% from baseline; or</p> <p>c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.</p> <p>PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.</p> <p>A treatment failure is defined as a patient who is</p> <p>(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or</p> <p>(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.</p> <p>The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).</p> <p>The authority application must be in writing and must include all of the following</p> <p>(1) A completed authority prescription form(s);</p>	

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				<p>(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);</p> <p>(3) A measurement of body weight at the time of application;</p> <p>(4) Results of genetic testing, if not previously submitted;</p> <p>(5) A family history of aHUS, if applicable;</p> <p>(6) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable;</p> <p>(7) A history of kidney transplant, if applicable (especially if required due to aHUS);</p> <p>(8) An inclusion of the individual consequences of recurrent disease;</p> <p>(9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;</p> <p>(10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;</p> <p>(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;</p> <p>(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.</p> <p>This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.</p>	
C14806	P14806	CN14806	Ustekinumab	<p>Complex refractory Fistulising Crohn disease</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p>	<p>Compliance with Authority Required procedures</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have demonstrated an adequate response to treatment with this drug; AND Must be treated by a gastroenterologist (code 87). or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The authority application must be made in writing and must include (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The most recent fistula assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.</p>	
C14808	P14808	CN14808	Ipilimumab	<p>Unresectable Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14808</p>

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				<p>Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.</p> <p>Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p>	
C14812	P14812	CN14812	Nivolumab with relatlimab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Initial treatment</p> <p>Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND</p> <p>Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND</p> <p>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND</p> <p>The condition must not be uveal melanoma; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition;</p> <p>Patient must weigh 40 kg or more;</p> <p>Patient must be at least 12 years of age.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14812
C14813	P14813	CN14813	Tebentafusp	<p>Advanced (unresectable or metastatic) uveal melanoma</p> <p>Initial treatment - day 1</p> <p>Patient must have HLA-A*02:01-positive disease; AND</p> <p>Patient must have uveal melanoma that has been confirmed either (i) histologically, (ii) cytologically; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have received prior systemic therapy for metastatic disease;</p> <p>Patient must be at least 18 years of age.</p> <p>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.</p> <p>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>Positive HLA-A*02 01 assessment must be documented in the patient's medical records.</p>	
C14815	P14815	CN14815	Nivolumab with relatlimab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14815
C14816	P14816	CN14816	Nivolumab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Initial treatment</p> <p>Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND</p> <p>Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14816
C14817	P14817	CN14817	Pembrolizumab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Initial treatment - 6 weekly treatment regimen</p>	Compliance with Authority Required procedures -

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				<p>Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND</p> <p>Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The treatment must not exceed a total of 3 doses under this restriction.</p>	Streamlined Authority Code 14817
C14818	P14818	CN14818	Pembrolizumab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Initial treatment - 3 weekly treatment regimen</p> <p>Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND</p> <p>Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The treatment must not exceed a total of 6 doses under this restriction.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14818
C14819	P14819	CN14819	Nivolumab with relatlimab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Initial treatment</p> <p>Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND</p> <p>Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND</p> <p>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND</p> <p>The condition must not be uveal melanoma; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition;</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14819

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must weigh 40 kg or more; Patient must be at least 12 years of age.</p>	
C14821	P14821	CN14821	Tebentafusp	<p>Advanced (unresectable or metastatic) uveal melanoma Initial treatment - day 8 Patient must have HLA-A*02:01-positive disease; AND Patient must have previously received PBS-subsidised initial day 1 treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. Positive HLA-A*02 01 assessment must be documented in the patient's medical records.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14821</p>
C14825	P14825	CN14825	Tebentafusp	<p>Advanced (unresectable or metastatic) uveal melanoma Initial treatment - day 15 Patient must have HLA-A*02:01-positive disease; AND Patient must have previously received PBS-subsidised initial day 8 treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14825</p>

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				<p>outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.</p> <p>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>Positive HLA-A*02 01 assessment must be documented in the patient's medical records.</p>	
C14828	P14828	CN14828	Fluoxetine	<p>Obsessive-compulsive disorder</p> <p>Patient must be receiving this drug under this restriction at a dose of 10 mg. or Patient must be receiving this drug under this restriction where a 10 mg strength is required to administer the total dose.</p>	
C14829	P14829	CN14829	Nivolumab with relatlimab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14829</p>
C14830	P14830	CN14830	Nivolumab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Induction treatment</p> <p>Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND</p> <p>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND</p> <p>The condition must not be ocular or uveal melanoma; AND</p> <p>The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.</p> <p>Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.</p> <p>Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14830</p>

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C14832	P14832	CN14832	Fluoxetine	Major depressive disorders Patient must be receiving this drug under this restriction at a dose of 10 mg. or Patient must be receiving this drug under this restriction where a 10 mg strength is required to administer the total dose.	
C14837	P14837	CN14837	Olmesartan with amlodipine and hydrochlorothiazide	Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.	
C14839	P14839	CN14839	Olmesartan with amlodipine	Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist. or The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.	
C14841	P14841	CN14841	Eprosartan	Drug interactions expected to occur with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures
C14842	P14842	CN14842	Desmopressin	Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; Patient must be 6 years of age or older; Patient must be one in whom an enuresis alarm is contraindicated.	Compliance with Authority Required procedures - Streamlined Authority Code 14842
C14843	P14843	CN14843	Liothyronine	Thyroid cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures -

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					Streamlined Authority Code 14843
C14844	P14844	CN14844	Liothyronine	Hypothyroidism The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be for replacement therapy; AND Patient must have documented intolerance to levothyroxine sodium. or Patient must have documented resistance to levothyroxine sodium.	Compliance with Authority Required procedures - Streamlined Authority Code 14844
C14847	P14847	CN14847	Perampanel	Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; Patient must be aged 12 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 14847
C14852	P14852	CN14852	Perampanel	Intractable partial epileptic seizures Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously been issued with an authority prescription for this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 14852
C14855	P14855	CN14855	Lamotrigine	Epileptic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. or Patient must be a woman of childbearing potential.	Compliance with Authority Required procedures - Streamlined Authority Code 14855
C14857	P14857	CN14857	Lacosamide	Intractable partial epileptic seizures Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Streamlined Authority Code 14857
C14858	P14858	CN14858	Linagliptin Saxagliptin Sitagliptin	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with metformin; or</p> <p>The treatment must be in combination with a sulfonylurea; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14858
C14859	P14859	CN14859	Dapagliflozin Empagliflozin	<p>Diabetes mellitus type 2</p> <p>Continuing treatment</p>	Compliance with Authority Required procedures -

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				<p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with metformin; AND</p> <p>The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND</p> <p>Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.</p>	Streamlined Authority Code 14859
C14862	P14862	CN14862	Alogliptin	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with metformin; or</p> <p>The treatment must be in combination with a sulfonylurea; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14862

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				A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.	
C14868	P14868	CN14868	Cyproterone	Moderate to severe androgenisation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation; Patient must be female; Patient must not be pregnant.	Compliance with Authority Required procedures - Streamlined Authority Code 14868
C14872	P14872	CN14872	Lanthanum Sucroferric oxyhydroxide	Hyperphosphataemia Maintenance following initiation and stabilisation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; or The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents; AND Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 14872
C14874	P14874	CN14874	Sodium acid phosphate	Hypophosphataemic rickets The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 14874
C14876	P14876	CN14876	Alogliptin with metformin	Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	Compliance with Authority Required procedures -

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				Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.	Streamlined Authority Code 14876
C14878	P14878	CN14878	Dapagliflozin with metformin Empagliflozin with metformin	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with a sulfonylurea; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14878
C14881	P14881	CN14881	Dapagliflozin with metformin	Diabetes mellitus type 2	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Empagliflozin with metformin	<p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with insulin; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p>	procedures - Streamlined Authority Code 14881
C14883	P14883	CN14883	Tiagabine Zonisamide	<p>Partial epileptic seizures</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14883
C14885	P14885	CN14885	Empagliflozin with linagliptin	Diabetes mellitus type 2	Compliance with Authority Required

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			Saxagliptin with dapagliflozin	Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	procedures - Streamlined Authority Code 14885
C14887	P14887	CN14887	Vildagliptin with metformin	Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.	Compliance with Authority Required procedures - Streamlined Authority Code 14887
C14888	P14888	CN14888	Linagliptin with metformin Saxagliptin with metformin Sitagliptin with metformin Vildagliptin with metformin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances	Compliance with Authority Required procedures - Streamlined Authority Code 14888

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				<p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.</p>	
C14891	P14891	CN14891	Linagliptin with metformin Saxagliptin with metformin Sitagliptin with metformin	<p>Diabetes mellitus type 2</p> <p>Continuing treatment</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND</p> <p>Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14891
C14894	P14894	CN14894	Linagliptin with metformin Sitagliptin with metformin Vildagliptin with metformin	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with insulin; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14894

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				<p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p>	
C14895	P14895	CN14895	Tamoxifen	<p>Breast cancer</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The condition must be hormone receptor positive.</p>	
C14898	P14898	CN14898	Alendronic acid with colecalciferol	<p>Osteoporosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient;</p> <p>Patient must be aged 70 years or older;</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14898
C14901	P14901	CN14901	Topiramate	<p>Migraine</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be for prophylaxis; AND</p>	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months; AND</p> <p>Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; or</p> <p>Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker; AND</p> <p>Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk. or</p> <p>Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.</p> <p>Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.</p>	Streamlined Authority Code 14901
C14903	P14903	CN14903	Vigabatrin	<p>Epileptic seizures</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14903
C14905	P14905	CN14905	Dapagliflozin Empagliflozin	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with metformin; or</p> <p>The treatment must be in combination with a sulfonylurea; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14905

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C14911	P14911	CN14911	Linagliptin Saxagliptin Sitagliptin	<p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.</p> <p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with metformin; AND</p> <p>The treatment must be in combination with a sulfonylurea; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14911

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.</p>	
C14912	P14912	CN14912	Testosterone	<p>Androgen deficiency</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must not have an established pituitary or testicular disorder; AND</p> <p>The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs;</p> <p>Patient must be aged 40 years or older;</p> <p>Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.</p> <p>Androgen deficiency is defined as</p> <p>(i) testosterone level of less than 6 nmol per litre; OR</p> <p>(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).</p> <p>Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.</p> <p>The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.</p> <p>The name of the specialist must be included in the authority application.</p>	Compliance with Authority Required procedures
C14913	P14913	CN14913	Testosterone	<p>Micropenis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient;</p> <p>Patient must be under 18 years of age;</p>	Compliance with Authority Required procedures

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application.	
C14914	P14914	CN14914	Bromocriptine	Acromegaly The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C14915	P14915	CN14915	Oxybutynin Propantheline	Detrusor overactivity The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C14918	P14918	CN14918	Cabergoline Quinagolide	Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom surgery is not indicated.	
C14921	P14921	CN14921	Sodium acid phosphate	Familial hypophosphataemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 14921
C14922	P14922	CN14922	Sodium acid phosphate	Hypercalcaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 14922
C14924	P14924	CN14924	Dapagliflozin with metformin Empagliflozin with metformin	Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND	Compliance with Authority Required procedures - Streamlined Authority Code 14924

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	
C14925	P14925	CN14925	Empagliflozin with metformin	Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.	Compliance with Authority Required procedures - Streamlined Authority Code 14925
C14931	P14931	CN14931	Topiramate	Seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have partial epileptic seizures; or Patient must have primary generalised tonic-clonic seizures; or Patient must have seizures of the Lennox-Gastaut syndrome; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; AND Patient must be unable to take a solid dose form of topiramate.	Compliance with Authority Required procedures - Streamlined Authority Code 14931
C14932	P14932	CN14932	Oxcarbazepine	Seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have partial epileptic seizures; or Patient must have primary generalised tonic-clonic seizures; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.	Compliance with Authority Required procedures - Streamlined Authority Code 14932
C14933	P14933	CN14933	Sitagliptin with metformin	Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.	Compliance with Authority Required procedures - Streamlined Authority Code 14933

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C14935	P14935	CN14935	Linagliptin with metformin	Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.	Compliance with Authority Required procedures - Streamlined Authority Code 14935
C14937	P14937	CN14937	Saxagliptin with metformin	Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin.	Compliance with Authority Required procedures - Streamlined Authority Code 14937
C14941	P14941	CN14941	Leflunomide	Severe active psoriatic arthritis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; or Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND The treatment must be initiated by a physician.	
C14942	P14942	CN14942	Leflunomide	Severe active rheumatoid arthritis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; or Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND The treatment must be initiated by a physician.	
C14943	P14943	CN14943	Anastrozole Letrozole	Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be hormone receptor positive.	
C14945	P14945	CN14945	Desmopressin	Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; Patient must be 6 years of age or older; Patient must be refractory to an enuresis alarm.	Compliance with Authority Required procedures - Streamlined Authority Code 14945
C14947	P14947	CN14947	Phenoxymethylpenicillin	Recurrent streptococcal infections (including rheumatic fever) The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be for prophylaxis.	
C14949	P14949	CN14949	Dapagliflozin Empagliflozin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or	Compliance with Authority Required procedures - Streamlined Authority Code 14949

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.</p>	
C14950	P14950	CN14950	Linagliptin Sitagliptin	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with insulin; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14950

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
C14954	P14954	CN14954	Linagliptin Saxagliptin Sitagliptin	Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 14954
C14955	P14955	CN14955	Testosterone	Pubertal induction The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; Patient must be under 18 years of age; Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C14956	P14956	CN14956	Testosterone	Constitutional delay of growth or puberty The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; Patient must be under 18 years of age; Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C14959	P14959	CN14959	Cabergoline	Pathological hyperprolactinaemia	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Quinagolide	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom radiotherapy is not indicated.	
C14962	P14962	CN14962	Sodium acid phosphate	Vitamin D-resistant rickets The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures - Streamlined Authority Code 14962
C14964	P14964	CN14964	Levetiracetam	Partial epileptic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or Patient must be a woman of childbearing potential; AND The treatment must not be given concomitantly with brivaracetam, except for cross titration.	Compliance with Authority Required procedures - Streamlined Authority Code 14964
C14965	P14965	CN14965	Medroxyprogesterone	Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive.	
C14969	P14969	CN14969	Eprosartan	Adverse effects occurring with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures
C14970	P14970	CN14970	Eprosartan	Drug interactions occurring with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures
C14972	P14972	CN14972	Desmopressin	Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; Patient must be 6 years of age or older;	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be refractory to an enuresis alarm.	Streamlined Authority Code 14972
C14973	P14973	CN14973	Topiramate	<p>Seizures</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have partial epileptic seizures; or</p> <p>Patient must have primary generalised tonic-clonic seizures; or</p> <p>Patient must have seizures of the Lennox-Gastaut syndrome; AND</p> <p>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14973
C14974	P14974	CN14974	Dapagliflozin Empagliflozin	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with insulin; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14974

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Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p>	
C14978	P14978	CN14978	Vildagliptin	<p>Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 14978

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.	
C14981	P14981	CN14981	Bromocriptine	Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had surgery for this condition with incomplete resolution.	
C14983	P14983	CN14983	Cabergoline Quinagolide	Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had radiotherapy for this condition with incomplete resolution.	
C14984	P14984	CN14984	Sevelamer	Hyperphosphataemia Maintenance following initiation and stabilisation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; or The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents; AND Patient must be undergoing dialysis for chronic kidney disease.	Compliance with Authority Required procedures - Streamlined Authority Code 14984
C14987	P14987	CN14987	Dapagliflozin with metformin	Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.	Compliance with Authority Required procedures - Streamlined Authority Code 14987
C14988	P14988	CN14988	Levetiracetam	Partial epileptic seizures	Compliance with Authority Required

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or</p> <p>Patient must be a woman of childbearing potential; AND</p> <p>Patient must be unable to take a solid dose form of levetiracetam; AND</p> <p>The treatment must not be given concomitantly with brivaracetam, except for cross titration.</p>	<p>procedures - Streamlined Authority Code 14988</p>
C14989	P14989	CN14989	Tamoxifen	<p>Reduction of breast cancer risk</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have a moderate or high risk of developing breast cancer; AND</p> <p>The treatment must not exceed a dose of 20 mg per day; AND</p> <p>The treatment must not exceed a lifetime maximum of 5 years for this condition.</p>	
C14990	P14990	CN14990	Medroxyprogesterone	<p>Endometrial cancer</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	
C14992	P14992	CN14992	Exemestane	<p>Breast cancer</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The condition must be hormone receptor positive.</p>	
C14993	P14993	CN14993	Alendronic acid with colecalciferol	<p>Established osteoporosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14993</p>

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	
C14994	P14994	CN14994	Minoxidil	Severe refractory hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be initiated by a consultant physician.	
C14997	P14997	CN14997	Teriparatide	Severe established osteoporosis Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously been issued with an authority prescription for this drug; AND The treatment must not exceed a lifetime maximum of 18 months therapy; AND Must be treated by a specialist. or Must be treated by a consultant physician.	Compliance with Authority Required procedures - Streamlined Authority Code 14997
C14999	P14999	CN14999	Vildagliptin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; or The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea. or Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 14999

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				<p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.</p>	
C15000	P15000	CN15000	Vildagliptin	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with insulin; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15000</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15001	P15001	CN15001	Pioglitazone	<p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with metformin; or</p> <p>The treatment must be in combination with a sulfonylurea; AND</p> <p>Patient must have a contraindication to a combination of metformin and a sulfonylurea; or</p> <p>Patient must not have tolerated a combination of metformin and a sulfonylurea; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15001</p>

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C15002	P15002	CN15002	Pioglitazone	<p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p> <p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with insulin; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p> <p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15002

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				peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.	
C15004	P15004	CN15004	Dutasteride with tamsulosin	Benign prostatic hyperplasia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia.	Compliance with Authority Required procedures - Streamlined Authority Code 15004
C15005	P15005	CN15005	Cabergoline Quinagolide	Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had surgery for this condition with incomplete resolution.	
C15006	P15006	CN15006	Oxybutynin	Detrusor overactivity The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be unable to tolerate oral oxybutynin. or Patient must be unable to swallow oral oxybutynin.	
C15007	P15007	CN15007	Medroxyprogesterone	Advanced breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive.	
C15009	P15009	CN15009	Eprosartan	Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	Compliance with Authority Required procedures
C15011	P15011	CN15011	Alendronic acid with colecalciferol	Osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; Patient must be aged 70 years or older; Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND	Compliance with Authority Required procedures - Streamlined Authority Code 15011

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				<p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p>	
C15012	P15012	CN15012	Desmopressin	<p>Cranial diabetes insipidus</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15012
C15014	P15014	CN15014	Pioglitazone	<p>Diabetes mellitus type 2</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The treatment must be in combination with metformin; AND</p> <p>The treatment must be in combination with a sulfonylurea; AND</p> <p>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.</p> <p>or</p> <p>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.</p> <p>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</p> <p>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.</p> <p>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15014

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</p> <p>(b) Had red cell transfusion within the previous 3 months.</p> <p>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.</p>	
C15015	P15015	CN15015	Testosterone	<p>Androgen deficiency</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have an established pituitary or testicular disorder; AND</p> <p>Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.</p> <p>The name of the specialist must be included in the authority application.</p>	Compliance with Authority Required procedures
C15017	P15017	CN15017	Bromocriptine	<p>Pathological hyperprolactinaemia</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have had radiotherapy for this condition with incomplete resolution.</p>	
C15018	P15018	CN15018	Dutasteride	<p>Benign prostatic hyperplasia</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have lower urinary tract symptoms; AND</p> <p>Patient must have moderate to severe benign prostatic hyperplasia; AND</p> <p>The treatment must be in combination with an alpha-antagonist.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15018
C15024	P15024	CN15024	Alendronic acid with colecalciferol	<p>Corticosteroid-induced osteoporosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15024

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				<p>Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p>	
C15025	P15025	CN15025	Desmopressin	<p>Primary nocturnal enuresis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient;</p> <p>Patient must be 6 years of age or older;</p> <p>Patient must be one in whom an enuresis alarm is contraindicated.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15025
C15028	P15028	CN15028	Bromocriptine	<p>Parkinson disease</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	
C15030	P15030	CN15030	Medroxyprogesterone	<p>Endometriosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.</p>	
C15031	P15031	CN15031	Exemestane	<p>Metastatic (Stage IV) breast cancer</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>The condition must be hormone receptor positive; AND</p> <p>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND</p> <p>Patient must be receiving PBS-subsidised everolimus concomitantly for this condition;</p> <p>Patient must not be pre-menopausal.</p>	
C15032	P15032	CN15032	Alendronic acid with colecalciferol	<p>Corticosteroid-induced osteoporosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15032

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p>	
C15035	P15035	CN15035	Alendronic acid with colecalciferol	<p>Established osteoporosis</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p> <p>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15035
C15036	P15036	CN15036	Tobramycin	<p>Proven Pseudomonas aeruginosa infection</p> <p>Continuing treatment</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must have cystic fibrosis; AND</p> <p>Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules; AND</p> <p>Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s);</p> <p>Patient must be 6 years of age or older.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15036
C15038	P15038	CN15038	Liothyronine	Hypothyroidism	Compliance with Authority Required procedures -

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				The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be severe hypothyroidism; AND The treatment must be for initiation of therapy only.	Streamlined Authority Code 15038
C15040	P15040	CN15040	Tobramycin	Proven Pseudomonas aeruginosa infection The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have cystic fibrosis; AND The treatment must be for management.	Compliance with Authority Required procedures - Streamlined Authority Code 15040
C15043	P15043	CN15043	Bromocriptine	Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom surgery is not indicated.	
C15044	P15044	CN15044	Bromocriptine	Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom radiotherapy is not indicated.	
C15047	P15047	CN15047	Dapagliflozin Empagliflozin	Chronic heart failure Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or	Compliance with Authority Required procedures - Streamlined Authority Code 15047

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15049	P15049	CN15049	Nirmatrelvir and ritonavir	<p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND</p> <p>Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.</p> <p>SARS-CoV-2 infection</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; or</p> <p>Patient must have received a positive rapid antigen test (RAT) result; AND</p> <p>Patient must have at least one sign or symptom attributable to COVID-19; AND</p> <p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>The treatment must be initiated within 5 days of symptom onset;</p> <p>Patient must be both:</p> <p>(i) at least 50 years of age, (ii) at high risk.</p> <p>For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions</p> <ol style="list-style-type: none"> 1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty, 3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m²), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15049</p>

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C15050	P15050	CN15050	Molnupiravir	<p>10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.</p> <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.</p> <p>For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p> <p>SARS-CoV-2 infection</p> <p>The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated; AND</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; or</p> <p>Patient must have received a positive rapid antigen test (RAT) result; AND</p> <p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>The treatment must be initiated within 5 days of symptom onset; or</p> <p>The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic;</p> <p>Patient must be at least 70 years of age.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15050</p>

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C15051	P15051	CN15051	Dapagliflozin Empagliflozin	<p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p> <p>For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.</p> <p>Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.</p> <p>Chronic heart failure</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug; AND</p> <p>Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or</p> <p>The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND</p> <p>Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15051

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C15055	P15055	CN15055	Molnupiravir	<p>SARS-CoV-2 infection</p> <p>The treatment must be for use when nirmatrelvir (& ritonavir is contraindicated; AND Patient must have received a positive polymerase chain reaction (PCR) test result; or Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset; Patient must be each of:</p> <p>(i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.</p> <p>For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions</p> <ol style="list-style-type: none"> 1. The patient is in residential aged care 2. The patient has disability with multiple comorbidities and/or frailty 3. Neurological conditions, including stroke and dementia and demyelinating conditions 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease 5. Heart failure, coronary artery disease, cardiomyopathies 6. Obesity (BMI greater than 30 kg/m²) 7. Diabetes type I or II, requiring medication for glycaemic control 8. Renal impairment (eGFR less than 60mL/min) 9. Cirrhosis 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above 11. Past COVID-19 infection episode resulting in hospitalisation. <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15055</p>

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15056	P15056	CN15056	Molnupiravir	<p>For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p> <p>For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.</p> <p>Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.</p> <p>SARS-CoV-2 infection</p> <p>The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated; AND</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; or</p> <p>Patient must have received a positive rapid antigen test (RAT) result; AND</p> <p>Patient must have at least one sign or symptom attributable to COVID-19; AND</p> <p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>The treatment must be initiated within 5 days of symptom onset;</p> <p>Patient must be both:</p> <p>(i) at least 50 years of age, (ii) at high risk.</p> <p>For the purpose of administering this restriction, high risk is defined as either a past COVID-19 infection episode resulting in hospitalisation, or the presence of at least two of the following conditions</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15056</p>

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty, 3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m²), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above.</p> <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.</p> <p>For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15062	P15062	CN15062	Molnupiravir	<p>For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.</p> <p>Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.</p> <p>SARS-CoV-2 infection</p> <p>The treatment must be for use when nirmatrelvir (&) ritonavir is contraindicated; AND Patient must have received a positive polymerase chain reaction (PCR) test result; or</p> <p>Patient must have received a positive rapid antigen test (RAT) result; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>Patient must satisfy at least one of the following criteria: (i) be moderately to severely immunocompromised with risk of progression to severe COVID-19 disease due to the immunocompromised status, (ii) has experienced past COVID-19 infection resulting in hospitalisation; AND</p> <p>The treatment must be initiated within 5 days of symptom onset; Patient must be at least 18 years of age.</p> <p>For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with</p> <ol style="list-style-type: none"> 1. Any primary or acquired immunodeficiency including 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. <ol style="list-style-type: none"> a. Haematologic neoplasms leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, 	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15062</p>

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				<p>b. Post-transplant solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),</p> <p>c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR</p> <p>2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received</p> <p>3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR</p> <p>4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR</p> <p>5. People with disability with multiple comorbidities and/or frailty.</p> <p>a. Chemotherapy or whole body radiotherapy,</p> <p>b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,</p> <p>c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),</p> <p>d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR</p> <p>3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received an anti-CD20 monoclonal antibody treatment, but criterion 2c above is not met; OR</p> <p>4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR</p> <p>5. People with disability with multiple comorbidities and/or frailty.</p> <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, available information about the test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p> <p>For the purpose of administering this restriction, the contraindications to nirmatrelvir (&) ritonavir can be found using the Liverpool COVID-19 Drug interaction checker or the TGA-approved Product Information for Paxlovid.</p> <p>Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records.</p>	
C15063	P15063	CN15063	Cemiplimab	<p>Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Continuing treatment - 3 weekly treatment regimen</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15063
C15065	P15065	CN15065	Inclisiran	<p>Familial heterozygous hypercholesterolaemia</p> <p>Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; or</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15065

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				<p>Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication; AND</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.</p>	
C15066	P15066	CN15066	Nusinersen	<p>Pre-symptomatic spinal muscular atrophy (SMA)</p> <p>Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 1 or 2 copies of the SMN2 gene - Loading doses</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND</p> <p>Patient must be untreated with gene therapy;</p> <p>Patient must be aged under 36 months prior to commencing treatment.</p> <p>Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i) confirmation of genetic diagnosis of SMA; and (ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)	
C15068	P15068	CN15068	Methotrexate	Severe active juvenile idiopathic arthritis Patient must be unsuitable for administration of an oral form of methotrexate for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 15068
C15069	P15069	CN15069	Nusinersen	Spinal muscular atrophy (SMA) Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; or Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND The treatment must be given concomitantly with best supportive care for this condition; AND	Compliance with Authority Required procedures

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				<p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug;</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.</p>	
C15070	P15070	CN15070	Lacosamide	<p>Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures</p> <p>Must be treated by a neurologist; or</p> <p>Must be treated by a paediatrician; or</p> <p>Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced; AND</p> <p>The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15070
C15071	P15071	CN15071	Golimumab	<p>Non-radiographic axial spondyloarthritis</p> <p>Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND</p> <p>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND</p> <p>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND</p> <p>The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND</p> <p>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND</p> <p>The treatment must not exceed a maximum of 16 weeks duration under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and</p> <p>(b) C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p>	

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C15077	P15077	CN15077	Alirocumab Evolocumab	<p>Familial heterozygous hypercholesterolaemia</p> <p>Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication; AND</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15077
C15079	P15079	CN15079	Evolocumab	<p>Non-familial hypercholesterolaemia</p> <p>Initial treatment</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>Patient must have symptomatic atherosclerotic cardiovascular disease; AND</p> <p>Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND</p> <p>Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or</p> <p>Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or</p> <p>Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or</p> <p>Patient must have diabetes mellitus with microalbuminuria; or</p> <p>Patient must have diabetes mellitus and be aged 60 years or more; or</p> <p>Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; or</p> <p>Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND</p> <p>Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; or</p> <p>Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; or</p> <p>Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND</p> <p>Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication; AND</p> <p>Must be treated by a specialist physician. or</p> <p>Must be treated by a physician who has consulted a specialist physician.</p> <p>Symptomatic atherosclerotic cardiovascular disease is defined as</p> <p>(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or</p> <p>(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or</p> <p>(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).</p> <p>The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.</p> <p>A clinically important product-related adverse event is defined as follows</p>	

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				<p>(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or</p> <p>(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or</p> <p>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</p> <p>If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retriial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retriial should not occur until CK has returned to normal.</p> <p>In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.</p> <p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <p>(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or</p> <p>(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or</p> <p>(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.</p> <p>One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event</p> <p>(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or</p> <p>(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years or more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.	
C15080	P15080	CN15080	Alirocumab Evolocumab	Non-familial hypercholesterolaemia Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran Patient must have previously received PBS-subsidised treatment with this drug for this condition; or Patient must have received PBS-subsidised treatment with a drug from the same pharmacological class as this drug for this PBS indication; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.	Compliance with Authority Required procedures - Streamlined Authority Code 15080
C15084	P15084	CN15084	Niraparib	High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test; AND The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 genes - this has been confirmed by a validated test; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; or The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment	Compliance with Authority Required procedures

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				<p>with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug class for the first time. or Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p> <p>Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.</p> <p>Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.</p>	
C15085	P15085	CN15085	Tebentafusp	<p>Advanced (unresectable or metastatic) uveal melanoma</p> <p>Continuing treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have previously received inpatient treatment with this drug for this condition in the public hospital setting; AND</p> <p>Patient must not receive PBS-subsidised treatment with this drug for this condition if it is no longer determined to be clinically beneficial by the treating clinician.</p> <p>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15085</p>

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C15089	P15089	CN15089	Lacosamide	<p>Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures</p> <p>The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND</p> <p>Must be treated by a neurologist; or</p> <p>Must be treated by a paediatrician; or</p> <p>Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND</p> <p>The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced; AND</p> <p>The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15089
C15092	P15092	CN15092	Evolocumab	<p>Familial heterozygous hypercholesterolaemia</p> <p>Initial treatment</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>The condition must have been confirmed by genetic testing; or</p> <p>The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND</p> <p>Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; or</p> <p>Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND</p> <p>Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; or</p> <p>Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; or</p> <p>Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND</p> <p>Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication; AND Must be treated by a specialist physician. or Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15094	P15094	CN15094	Cemiplimab	<p>patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retriial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retriial should not occur until CK has returned to normal.</p> <p>In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.</p> <p>The following must be stated at the time of application and documented in the patient's medical records</p> <ul style="list-style-type: none"> (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia <p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <ul style="list-style-type: none"> (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. 	<p>Compliance with Authority Required procedures - Streamlined Authority Code 15094</p>

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C15095	P15095	CN15095	Risdiplam	<p>The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 7 doses under this restriction.</p> <p>Spinal muscular atrophy (SMA) Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) Patient must have previously received PBS-subsidised treatment with this drug for this condition; or Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND The treatment must be given concomitantly with best supportive care for this condition; AND Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy; Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required. The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The approved Product Information recommended dosing is as follows (i) 16 days to less than 2 months of age 0.15 mg/kg (ii) 2 months to less than 2 years of age 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more 5 mg In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to 1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.	
C15101	P15101	CN15101	Golimumab	Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND	Compliance with Written Authority Required procedures

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				<p>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND</p> <p>The treatment must not exceed a maximum of 16 weeks with this drug under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p> <p>The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and</p> <p>(b) C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not</p>	

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C15103	P15103	CN15103	Certolizumab pegol	<p>conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The baseline BASDAI score and CRP level must also be documented in the patient's medical records.</p> <p>Non-radiographic axial spondyloarthritis</p> <p>Initial treatment - Initial 3 (Resumption of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have one or more of the following:</p> <p>(a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND</p> <p>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND</p> <p>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND</p> <p>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND</p> <p>The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND</p> <p>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND</p>	Compliance with Authority Required procedures

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				<p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and</p> <p>(b) C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p>	
C15104	P15104	CN15104	Upadacitinib	<p>Non-radiographic axial spondyloarthritis</p> <p>Initial treatment - Initial 1 (New patient)</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND</p> <p>Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND</p> <p>Patient must have one or more of the following:</p> <p>(a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND</p> <p>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND</p> <p>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND</p> <p>The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND</p> <p>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND</p> <p>The treatment must not exceed a maximum of 16 weeks with this drug under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p> <p>The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and</p> <p>(b) C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.</p>	

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C15106	P15106	CN15106	Alirocumab	<p>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The baseline BASDAI score and CRP level must also be documented in the patient's medical records.</p> <p>Familial heterozygous hypercholesterolaemia</p> <p>Initial treatment</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>The condition must have been confirmed by genetic testing; or</p> <p>The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND</p> <p>Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; or</p> <p>Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND</p> <p>Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; or</p> <p>Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND</p> <p>Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of:</p> <p>(i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication; AND</p> <p>Must be treated by a specialist physician.</p> <p>Symptomatic atherosclerotic cardiovascular disease is defined as</p> <p>(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or</p> <p>(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or</p> <p>(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).</p> <p>The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.</p> <p>A clinically important product-related adverse event is defined as follows</p> <p>(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or</p> <p>(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or</p>	

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				<p>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</p> <p>If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retriial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retriial should not occur until CK has returned to normal.</p> <p>In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.</p> <p>The following must be stated at the time of application and documented in the patient's medical records</p> <p>(i) the qualifying Dutch Lipid Clinic Network Score; or</p> <p>(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia</p> <p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <p>(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or</p> <p>(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or</p> <p>(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.</p>	
C15107	P15107	CN15107	Alirocumab	<p>Non-familial hypercholesterolaemia</p> <p>Initial treatment</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>Patient must have symptomatic atherosclerotic cardiovascular disease; AND</p> <p>Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre prior to commencing treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9); AND</p>	Compliance with Authority Required procedures

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				<p>Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or</p> <p>Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or</p> <p>Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or</p> <p>Patient must have diabetes mellitus with microalbuminuria; or</p> <p>Patient must have diabetes mellitus and be aged 60 years or more; or</p> <p>Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; or</p> <p>Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND</p> <p>Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; or</p> <p>Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; or</p> <p>Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND</p> <p>Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9), (ii) inclisiran, for this PBS indication; AND</p> <p>Must be treated by a specialist physician.</p> <p>Symptomatic atherosclerotic cardiovascular disease is defined as (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or</p>	

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				<p>(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or</p> <p>(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).</p> <p>The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.</p> <p>A clinically important product-related adverse event is defined as follows</p> <p>(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or</p> <p>(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or</p> <p>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</p> <p>If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreat should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retreat should not occur until CK has returned to normal.</p> <p>In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.</p>	

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				<p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <ul style="list-style-type: none"> (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. <p>One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event</p> <ul style="list-style-type: none"> (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years or more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher. 	
C15108	P15108	CN15108	Niraparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules</p> <p>The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test; AND</p> <p>The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 genes - this has been confirmed by a validated test; AND</p>	Compliance with Authority Required procedures

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C15109	P15109	CN15109	Niraparib	<p>Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; or</p> <p>The condition must have both:</p> <p>(i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug class for the first time. or Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p> <p>Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.</p> <p>Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.</p>	Compliance with Authority Required procedures

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				<p>Patient must be undergoing treatment with this drug class for the first time. or Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p> <p>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.</p>	
C15110	P15110	CN15110	Inclisiran	<p>Non-familial hypercholesterolaemia</p> <p>Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have previously received PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication; AND</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15110
C15112	P15112	CN15112	Nusinersen	<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p>	Compliance with Authority Required procedures

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				<p>Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug;</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.</p>	
C15115	P15115	CN15115	Ondansetron	<p>Nausea and vomiting</p> <p>The condition must be associated with radiotherapy being used to treat malignancy. or</p> <p>The condition must be associated with cytotoxic chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15115
C15116	P15116	CN15116	Nusinersen	<p>Pre-symptomatic spinal muscular atrophy (SMA)</p> <p>Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene - Loading doses</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical</p>	Compliance with Authority Required procedures

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C15117	P15117	CN15117	Certolizumab pegol	<p>practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND</p> <p>Patient must be untreated with gene therapy;</p> <p>Patient must be aged under 36 months prior to commencing treatment.</p> <p>Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:</p> <p>(i) confirmation of genetic diagnosis of SMA; and</p> <p>(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p>	<p>Compliance with Written Authority Required procedures</p>

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				<p>Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction; AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L.</p>	

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				<p>The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The baseline BASDAI score and CRP level must also be documented in the patient's medical records.</p>	
C15118	P15118	CN15118	Fluticasone propionate with salmeterol	<p>Asthma</p> <p>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 15118
C15122	P15122	CN15122	Inclisiran	<p>Familial heterozygous hypercholesterolaemia</p> <p>Initial treatment</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>The condition must have been confirmed by genetic testing; or</p> <p>The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND</p> <p>Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; or</p>	Compliance with Authority Required procedures

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				<p>Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; or Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; or Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication; AND Must be treated by a specialist physician. or Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse</p>	

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				<p>events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.</p> <p>A clinically important product-related adverse event is defined as follows</p> <p>(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or</p> <p>(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or</p> <p>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</p> <p>If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreat should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retreat should not occur until CK has returned to normal.</p> <p>In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.</p> <p>The following must be stated at the time of application and documented in the patient's medical records</p> <p>(i) the qualifying Dutch Lipid Clinic Network Score; or</p> <p>(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia</p> <p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <p>(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or</p> <p>(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or</p>	

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				(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.	
C15124	P15124	CN15124	Acalabrutinib	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First line drug treatment of this indication - in combination with obinutuzumab The condition must be untreated with drug treatment at the time of the first dose of this drug; or Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND The treatment must be initiated as a monotherapy for 1 Cycle with treatment in combination with obinutuzumab from Cycle 2 to 7 (refer to Product Information for timing of obinutuzumab and acalabrutinib doses) after which treatment must be monotherapy; AND Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug. or Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.</p>	Compliance with Authority Required procedures
C15125	P15125	CN15125	Golimumab	<p>Non-radiographic axial spondyloarthritis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction; AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p>	Compliance with Authority Required procedures

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C15126	P15126	CN15126	Certolizumab pegol	<p>An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following</p> <p>(a) a CRP measurement no greater than 10 mg per L; or</p> <p>(b) a CRP measurement reduced by at least 20% from baseline.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.</p> <p>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.</p> <p>Non-radiographic axial spondyloarthritis</p> <p>Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND</p> <p>Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.</p> <p>A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.</p>	Compliance with Authority Required procedures

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				<p>An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following</p> <ul style="list-style-type: none"> (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. <p>The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <ul style="list-style-type: none"> (a) the BASDAI score; and (b) the C-reactive protein (CRP) level. 	
C15127	P15127	CN15127	Secukinumab	<p>Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient)</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND</p> <p>Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND</p> <p>Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND</p> <p>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND</p>	Compliance with Written Authority Required procedures

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				<p>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND</p> <p>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND</p> <p>The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND</p> <p>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND</p> <p>Patient must not receive more than 20 weeks of treatment under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.</p> <p>State in the application whether a loading dose regimen is intended or not.</p> <p>Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.</p> <p>Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p>	

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				<p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p> <p>The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and</p> <p>(b) C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The baseline BASDAI score and CRP level must also be documented in the patient's medical records.</p>	
C15128	P15128	CN15128	Upadacitinib	<p>Non-radiographic axial spondyloarthritis</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have commenced treatment with this biological medicine for this condition prior to 1 August 2023; AND</p> <p>The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND</p>	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND</p> <p>Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND</p> <p>Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND</p> <p>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND</p> <p>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND</p> <p>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND</p> <p>The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND</p> <p>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND</p> <p>The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</p> <p>If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.</p> <p>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</p> <p>If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.</p>	

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and</p> <p>(b) C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>The baseline BASDAI score and CRP level must also be documented in the patient's medical records.</p>	
C15131	P15131	CN15131	Niraparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules</p> <p>Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15132	P15132	CN15132	Inclisiran	<p>Familial heterozygous hypercholesterolaemia</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024; AND</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; or</p> <p>The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; or</p> <p>Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND</p> <p>Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND</p> <p>Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication; AND</p>	Compliance with Authority Required procedures

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				<p>Must be treated by a specialist physician. or Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retriial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retriial should not have occurred until CK had returned to normal.</p> <p>In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.</p> <p>The following must be stated at the time of application and documented in the patient's medical records</p> <ul style="list-style-type: none"> (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia <p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <ul style="list-style-type: none"> (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p>	
C15133	P15133	CN15133	Acalabrutinib	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) First line drug treatment of this indication - as monotherapy The condition must be untreated with drug treatment at the time of the first dose of this drug; or Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND</p>	Compliance with Authority Required procedures

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C15135	P15135	CN15135	Golimumab	<p>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND</p> <p>Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug. or</p> <p>Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug.</p> <p>Non-radiographic axial spondyloarthritis</p> <p>Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND</p> <p>The treatment must not exceed a maximum of 16 weeks with this drug under this restriction; AND</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis; AND</p> <p>Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle.</p> <p>An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.</p> <p>A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.</p> <p>An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following</p> <p>(a) a CRP measurement no greater than 10 mg per L; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15137	P15137	CN15137	Secukinumab	<p>(b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.</p> <p>Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND Patient must not receive more than 20 weeks of treatment under this restriction; AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.</p>	Compliance with Authority Required procedures

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C15138	P15138	CN15138	Fluticasone propionate with salmeterol	<p>A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.</p> <p>An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following</p> <p>(a) a CRP measurement no greater than 10 mg per L; or</p> <p>(b) a CRP measurement reduced by at least 20% from baseline.</p> <p>The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.</p> <p>BASDAI scores and CRP levels must be documented in the patient's medical records.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(a) the BASDAI score; and</p> <p>(b) the C-reactive protein (CRP) level.</p> <p>The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter.</p> <p>State in the application whether a loading dose regimen is intended or not.</p> <p>Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing.</p> <p>Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.</p>	Compliance with Authority Required procedures -

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.	Streamlined Authority Code 15138
C15140	P15140	CN15140	Upadacitinib	<p>Non-radiographic axial spondyloarthritis</p> <p>Continuing treatment</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following</p> <p>(a) a CRP measurement no greater than 10 mg per L; or</p> <p>(b) a CRP measurement reduced by at least 20% from baseline.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.</p> <p>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.</p>	Compliance with Authority Required procedures
C15141	P15141	CN15141	Olaparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation)</p> <p>The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test; AND</p>	Compliance with Authority Required procedures

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				<p>The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 genes - this has been confirmed by a validated test; AND</p> <p>Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; or</p> <p>The condition must have both:</p> <p>(i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug class for the first time. or</p> <p>Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p> <p>Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.</p> <p>Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.</p>	
C15142	P15142	CN15142	Niraparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules</p> <p>The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase:</p> <p>Initial first-line maintenance therapy (BRCA1/2 gene mutation); AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15144	P15144	CN15144	Inclisiran	<p>The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.</p> <p>Non-familial hypercholesterolaemia Initial treatment</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have symptomatic atherosclerotic cardiovascular disease; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or Patient must have diabetes mellitus with microalbuminuria; or Patient must have diabetes mellitus and be aged 60 years or more; or Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; or Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; or Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; or Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; AND</p>	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication; AND</p> <p>Must be treated by a specialist physician. or</p> <p>Must be treated by a physician who has consulted a specialist physician.</p> <p>Symptomatic atherosclerotic cardiovascular disease is defined as</p> <p>(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or</p> <p>(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or</p> <p>(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).</p> <p>The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.</p> <p>A clinically important product-related adverse event is defined as follows</p> <p>(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or</p> <p>(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or</p> <p>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</p> <p>If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.</p> <p>In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.</p> <p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <ul style="list-style-type: none"> (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. <p>One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event</p> <ul style="list-style-type: none"> (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years or more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher. 	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15149	P15149	CN15149	Upadacitinib	<p>Non-radiographic axial spondyloarthritis</p> <p>Initial treatment - Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND</p> <p>Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle; AND</p> <p>The treatment must not exceed a maximum of 16 weeks with this drug under this restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.</p> <p>A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.</p> <p>An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following</p> <p>(a) a CRP measurement no greater than 10 mg per L; or</p> <p>(b) a CRP measurement reduced by at least 20% from baseline.</p> <p>The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.</p> <p>BASDAI scores and CRP levels must be documented in the patient's medical records.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The following must be provided at the time of application and documented in the patient's medical records (a) the BASDAI score; and (b) the C-reactive protein (CRP) level.	
C15150	P15150	CN15150	Upadacitinib	Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Resumption of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction; AND Must be treated by a rheumatologist. or	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</p> <p>The following must be provided at the time of application and documented in the patient's medical records</p> <p>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and</p> <p>(b) C-reactive protein (CRP) level greater than 10 mg per L.</p> <p>The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.</p> <p>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.</p> <p>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.</p>	
C15153	P15153	CN15153	Inclisiran	<p>Non-familial hypercholesterolaemia</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024; AND</p> <p>The treatment must be in conjunction with dietary therapy and exercise; AND</p> <p>Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; or</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; or</p> <p>Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND</p> <p>Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication; AND</p> <p>Must be treated by a specialist physician. or</p> <p>Must be treated by a physician who has consulted a specialist physician.</p>	

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				<p>Symptomatic atherosclerotic cardiovascular disease is defined as</p> <ul style="list-style-type: none">(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography)); or(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). <p>The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.</p> <p>A clinically important product-related adverse event is defined as follows</p> <ul style="list-style-type: none">(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. <p>If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least</p>	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>4 weeks, or if the creatine kinase (CK) level was elevated, the retriial should not have occurred until CK had returned to normal.</p> <p>In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.</p> <p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment</p> <ul style="list-style-type: none"> (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. <p>One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event</p> <ul style="list-style-type: none"> (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years or more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher. <p>A patient may qualify for PBS-subsidised treatment under this restriction once only.</p> <p>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15155	P15155	CN15155	Niraparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules</p> <p>Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.</p>	Compliance with Authority Required procedures
C15158	P15158	CN15158	Secukinumab	<p>Non-radiographic axial spondyloarthritis</p> <p>Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND</p> <p>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND</p> <p>Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND</p> <p>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND</p> <p>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND</p> <p>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND</p> <p>The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND</p> <p>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND</p>	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				<p>Patient must not receive more than 20 weeks of treatment under this restriction; AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be provided at the time of application and documented in the patient's medical records (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The stated maximum quantity of 5 with zero repeats is intended for a patient undergoing the loading dose regimen of 150 mg administered at weeks 0, 1, 2, 3, and 4 (a total of 5 doses) followed by monthly administration thereafter. State in the application whether a loading dose regimen is intended or not. Where a loading dose regimen is intended, request a maximum quantity of 5 and zero repeats to cover doses at weeks 0, 1, 2, 3 and 4. Doses at week 8, 12, and 16 can be sought under the relevant 'Balance of supply' listing. Where no loading dose regimen is intended, request a maximum quantity of 1 and seek an increase in the number of repeats from zero to 4 repeats to cover dosing at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.</p>	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15160	P15160	CN15160	Niraparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules</p> <p>The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase:</p> <p>Initial first-line maintenance therapy (BRCA1/2 gene mutation); AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.</p>	Compliance with Authority Required procedures
C15162	P15162	CN15162	Niraparib	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules</p> <p>The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the BRCA1/2 gene(s) - this has been confirmed by a validated test; AND</p> <p>Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must be undergoing treatment with this drug class for the first time. or</p> <p>Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p> <p>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.</p>	Compliance with Authority Required procedures

Part 2—Variation rules

2 Variation rules

The following table sets out variation rules for variations codes, for the purposes of sections 15 and 16.

Variation Code	Listed Drug	Variation Rules
V4077	Granisetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V4118	Granisetron Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V4139	Granisetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5618	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5721	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5743	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5778	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V7273	Icatibant	Increased maximum quantities will be limited to 12 injections per authority prescription.
V7274	Icatibant	Increased maximum quantities will be limited to 12 injections per authority prescription.
V7433	Axitinib	Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.
V8588	Axitinib	Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.
V9041	Pegvisomant	No increase in the maximum quantity or number of units may be authorised for the loading dose.
V9919	Sodium phenylbutyrate	An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m ² /day in patients weighing more than 20 kg.
V9993	Sodium	An increase in the maximum quantity will be authorised to provide for up to one month's supply at a dose of up to 600 mg/kg/day in patients weighing less than 20

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	phenylbutyrate	kg and up to 13 g/m ² /day in patients weighing more than 20 kg.
V10745	Fentanyl Methadone	<p>Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10747	Fentanyl Methadone	<p>Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment</p> <p>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or</p> <p>(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or</p> <p>(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10748	Buprenorphine Morphine Oxycodone Oxycodone with naloxone Tapentadol Tramadol	<p>Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment</p> <p>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or</p> <p>(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or</p> <p>(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10751	Fentanyl Methadone	<p>Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment</p>

Clause 1

- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

V10752	Buprenorphine Morphine Oxycodone Oxycodone with naloxone Tapentadol Tramadol	<p>Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment</p> <ul style="list-style-type: none"> (i) is less than 12 months; or (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10755	Buprenorphine Morphine Oxycodone Oxycodone with naloxone Tapentadol Tramadol	<p>Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>

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V10756	Morphine	<p>Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10762	Morphine	<p>Authorities for increased maximum quantities and/or repeats must only be considered for</p> <p>(i) severe disabling pain associated with proven malignant neoplasia; or</p> <p>(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or</p> <p>(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or</p> <p>(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10764	Codeine Codeine with paracetamol Hydromorphone Morphine Oxycodone Tramadol	<p>Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for</p> <p>(i) severe disabling pain associated with malignant neoplasia; or</p> <p>(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or</p> <p>(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or</p> <p>(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or</p> <p>(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.</p>

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		<p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10765	Morphine	<p>Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10770	Hydromorphone Morphine	<p>Authorities for increased maximum quantities and/or repeats must only be considered for</p> <p>(i) severe disabling pain associated with proven malignant neoplasia; or</p> <p>(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or</p> <p>(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or</p> <p>(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10771	Codeine Codeine with paracetamol Oxycodone Tramadol	<p>Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10772	Codeine Codeine with paracetamol	<p>Authorities for increased maximum quantities and/or repeats must only be considered for</p> <p>(i) severe disabling pain associated with proven malignant neoplasia; or</p>

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	Oxycodone Tramadol	<p>(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or</p> <p>(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or</p> <p>(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10775	Morphine	<p>Authorities for increased maximum quantities and/or repeats must only be considered for</p> <p>(i) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or</p> <p>(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or</p> <p>(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10777	Hydromorphone Morphine	<p>Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.</p> <p>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.</p> <p>Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>
V10814	Morphine	<p>Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial</p>

authority approval and the total duration of non-PBS and PBS opioid analgesic treatment

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

V10837 Morphine

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

V10858 Morphine

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with

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the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

V10890 Oxycodone

Authorities for increased maximum quantities and/or repeats must only be considered for

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

V10891 Morphine

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

V10910 Oxycodone

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

V11696 Fentanyl

Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

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	Methadone	Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
V11697	Hydromorphone Morphine	Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
V11753	Buprenorphine Morphine Oxycodone Oxycodone with naloxone	Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
V14812	Nivolumab with relatlimab	Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.
V14815	Nivolumab with relatlimab	Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.
V14819	Nivolumab with relatlimab	Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.
V14829	Nivolumab with relatlimab	Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.
V14842	Desmopressin	No more than twice the maximum quantity will be authorised.
V14945	Desmopressin	No increase in the maximum quantity or number of units may be authorised.
V14972	Desmopressin	No more than twice the maximum quantity will be authorised.
V15025	Desmopressin	No increase in the maximum quantity or number of units may be authorised.