

**PB 26 of 2024**

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

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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  The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.  A maximum of 6 cycles will be authorised under this restriction in a lifetime.  Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.  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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.  Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.  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.  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.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures |
| C13004 | P13004 | CN13004 | Trastuzumab emtansine | Early HER2 positive breast cancer  Initial adjuvant treatment  The treatment must be prescribed within 12 weeks after surgery; AND  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  Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery; 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; AND  The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined.  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  (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.  The pathology report 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 |
| C13006 | P13006 | CN13006 | Ponatinib | Chronic Myeloid Leukaemia (CML)  Subsequent continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have maintained a major cytogenic response of less than 35% Philadelphia positive bone marrow cells at 12 month intervals. or  Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% on the international scale at 12 month intervals.  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. | Compliance with Authority Required procedures |
| C13007 | P13007 | CN13007 | Lapatinib | 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  The treatment must be in combination with capecitabine; AND  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  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  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  Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; AND  The treatment must be the sole PBS-subsidised anti-HER2 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.  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  (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  (ii) date of last treatment with a taxane and total number of cycles; or  (iii) dates of treatment with trastuzumab and pertuzumab; or  (iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or  (v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab  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.  All reports 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.  If the application is submitted through HPOS upload or mail, it must include  (a) a completed authority prescription form; and  (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). | Compliance with Written Authority Required procedures |
| C13008 | P13008 | CN13008 | Zanubrutinib | Waldenstrom macroglobulinaemia  Initial treatment  The condition must have relapsed or be refractory to at least one prior chemo-immunotherapy; or  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  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND  Patient must be untreated with a Bruton's tyrosine kinase inhibitor for this condition. or  Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this condition. | Compliance with Authority Required procedures |
| C13010 | P13010 | CN13010 | Azacitidine | Acute Myeloid Leukaemia  Initial treatment  The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination; AND  The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.  The following reports must be documented in the patient's medical records  (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and  (b) full blood examination report. | Compliance with Authority Required procedures |
| 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.  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.  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.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.  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 that the patient is not undergoing or has not undergone a stem cell transplant; and  (b) confirmation that the patient does not have progressive disease; and  (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  (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.  All reports must be documented in the patient's medical records.  If the application is submitted through HPOS upload or mail, it must include  (a) a completed authority prescription form; and  (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). | Compliance with Written Authority Required procedures |
| C13015 | P13015 | CN13015 | Azacitidine | 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 |
| 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.  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. | Compliance with Authority Required procedures |
| 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 cytogenic 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  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  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).  Blast crisis is defined as either  1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  2. Extramedullary involvement other than spleen and liver.  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  (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  (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  (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.  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).  Up to a maximum of 18 months of treatment may be authorised under this initial restriction. | Compliance with Written Authority Required procedures |
| C13029 | P13029 | CN13029 | Azacitidine | Chronic Myelomonocytic Leukaemia  Initial treatment  The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report; AND  The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.  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  (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  (b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority  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 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  No more than 3 cycles will be authorised under this restriction in a patient's lifetime. | Compliance with Written Authority Required procedures |
| C13030 | P13030 | CN13030 | Ponatinib | Chronic Myeloid Leukaemia (CML)  Initial treatment  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  Patient must have failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority. or  Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority. or  Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority.  Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as  1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either  (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  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; 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 imatinib or dasatinib or nilotinib therapy; OR  4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or 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 imatinib or 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  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).  Blast crisis is defined as either  1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  2. Extramedullary involvement other than spleen and liver.  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  (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  (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  (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and  (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.  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).  Up to a maximum of 18 months of treatment may be authorised under this initial restriction. | Compliance with Written Authority Required procedures |
| C13034 | P13034 | CN13034 | Diroximel fumarate | Multiple sclerosis  Continuing treatment  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 previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug.  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 13034 |
| C13035 | P13035 | CN13035 | Abemaciclib | 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 one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; 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 |
| C13036 | P13036 | CN13036 | Abemaciclib | 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 |
| C13037 | P13037 | CN13037 | 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; AND  Patient must require dosage reduction requiring a pack of 42 tablets;  Patient must not be premenopausal. | Compliance with Authority Required procedures |
| C13039 | P13039 | CN13039 | Infliximab | Complex refractory Fistulising Crohn disease  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  (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. | Compliance with Authority Required procedures |
| C13040 | P13040 | CN13040 | Infliximab | Severe psoriatic arthritis  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 psoriatic arthritis; 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'. | Compliance with Authority Required procedures |
| C13043 | P13043 | CN13043 | Infliximab | Severe psoriatic arthritis  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  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 this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  The treatment must have both:   (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  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).  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).  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. | Compliance with Authority Required procedures |
| C13045 | P13045 | CN13045 | Infliximab | 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  (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. | Compliance with Authority Required procedures |
| 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 |
| C13056 | P13056 | CN13056 | Infliximab | Complex refractory Fistulising Crohn disease  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  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  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.  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. | Compliance with Authority Required procedures |
| C13058 | P13058 | CN13058 | Infliximab | Severe chronic plaque psoriasis  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 dermatologist; 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'. | Compliance with Authority Required procedures |
| C13061 | P13061 | CN13061 | Infliximab | Moderate to severe ulcerative colitis  Balance of supply for Initial treatment, Continuing treatment - subcutaneous form  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 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  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  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  The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form;  Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
| C13066 | P13066 | CN13066 | Palbociclib | 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.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures |
| C13068 | P13068 | CN13068 | Infliximab | Severe Crohn disease  Balance of supply for Initial treatment, Continuing treatment - subcutaneous form  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 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  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  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  The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form;  Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
| C13069 | P13069 | CN13069 | Infliximab | Severe active rheumatoid arthritis  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  (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. | Compliance with Authority Required procedures |
| C13070 | P13070 | CN13070 | Bimekizumab | Severe chronic plaque psoriasis  Grandfathered patient - Face, hand, foot or Whole body - Balance of Supply  Must be treated by a dermatologist; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  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  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  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C13072 | P13072 | CN13072 | Diroximel fumarate | Multiple sclerosis  Initial treatment  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13072 |
| C13074 | P13074 | CN13074 | Ribociclib | 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 one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; 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; AND  Patient must require dosage reduction requiring a pack of 42 tablets;  Patient must not be premenopausal. | Compliance with Authority Required procedures |
| C13077 | P13077 | CN13077 | Infliximab | Ankylosing spondylitis  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  (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. | Compliance with Authority Required procedures |
| C13078 | P13078 | CN13078 | Infliximab | Severe chronic plaque psoriasis  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  (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. | Compliance with Authority Required procedures |
| C13079 | P13079 | CN13079 | Infliximab | Severe chronic plaque psoriasis  Continuing treatment (whole body, or, face/hand/foot) with subcutaneous form or switching from intravenous form to subcutaneous form  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  The treatment must have both:   (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  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.  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).  Where the condition is affecting the whole body, an adequate response to treatment is defined as  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.  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  (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  (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.  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. | Compliance with Authority Required procedures |
| C13080 | P13080 | CN13080 | Infliximab | Severe Crohn disease  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  (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. | Compliance with Authority Required procedures |
| C13082 | P13082 | CN13082 | Paliperidone | Schizophrenia  Patient must have previously received and be stabilised on PBS-subsidised paliperidone three-monthly injection for at least one cycle. or  Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months. | Compliance with Authority Required procedures - Streamlined Authority Code 13082 |
| C13084 | P13084 | CN13084 | Ribociclib | 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 one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; 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 |
| 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, (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'. | Compliance with Authority Required procedures |
| C13096 | P13096 | CN13096 | Infliximab | 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'. | Compliance with Authority Required procedures |
| C13097 | P13097 | CN13097 | Infliximab | Severe psoriatic arthritis  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  (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. | Compliance with Authority Required procedures |
| C13099 | P13099 | CN13099 | 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  Patient must require dosage reduction requiring a pack of 21 tablets; 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 |
| C13104 | P13104 | CN13104 | Infliximab | Severe active rheumatoid arthritis  Balance of supply for Initial treatment, Continuing treatment - subcutaneous form  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 Initial treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); or  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  The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND  The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; or  The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form;  Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
| C13105 | P13105 | CN13105 | Ribociclib | 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 one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; 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; AND  Patient must require dosage reduction requiring a pack of 21 tablets;  Patient must not be premenopausal. | Compliance with Authority Required procedures |
| C13122 | P13122 | CN13122 | 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 13122 |
| C13127 | P13127 | CN13127 | Ruxolitinib | High risk and intermediate-2 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.  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.  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 Authority Required procedures |
| 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  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). | Compliance with Authority Required procedures |
| C13152 | P13152 | CN13152 | Sunitinib | 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  (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. | Compliance with Written Authority Required procedures |
| 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.  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. | Compliance with Authority Required procedures |
| 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  (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 Authority Required procedures |
| C13175 | P13175 | CN13175 | Sonidegib  Vismodegib | Metastatic or locally advanced basal cell carcinoma (BCC)  Initial treatment  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  (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  (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and  (c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.  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.  (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 and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records. | Compliance with Written Authority Required procedures |
| C13177 | P13177 | CN13177 | Vorinostat | Cutaneous T-cell lymphoma  Initial treatment  Patient must have received systemic treatment with chemotherapy; AND  Patient must demonstrate relapsed or chemotherapy-refractory disease; AND  Patient must be ineligible for stem cell transplant; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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). | Compliance with Authority Required procedures |
| C13179 | P13179 | CN13179 | Brentuximab vedotin | CD30 positive cutaneous T-cell lymphoma  Initial treatment  Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma; AND  Patient must have CD30 positivity of at least 3% of malignant cells; AND  Patient must have a diagnosis of mycosis fungoides; or  Patient must have a diagnosis of Sezary syndrome; or  Patient must have a diagnosis of primary cutaneous anaplastic large cell lymphoma; AND  Patient must have received prior systemic treatment for this condition; AND  The condition must be relapsed or refractory; AND  The treatment must not exceed 4 cycles under this restriction in a lifetime; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.  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 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  (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  (c) Date of commencement and completion of the most recent prior systemic treatment.  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 |
| C13181 | P13181 | CN13181 | Brentuximab vedotin | CD30 positive cutaneous T-cell lymphoma  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have achieved an objective response with this drug; AND  Patient must not have developed disease progression while receiving PBS-subsidised 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 treatment must not exceed 12 cycles under this restriction in a lifetime.  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. | Compliance with Authority Required procedures |
| C13182 | P13182 | CN13182 | Brentuximab vedotin | CD30 positive systemic anaplastic large cell lymphoma  Initial treatment  The treatment must be for curative intent; AND  Patient must have undergone appropriate prior front-line curative intent chemotherapy; AND  Patient must demonstrate relapsed or chemotherapy-refractory disease; AND  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  The treatment must not exceed 4 cycles 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 and must include  (a) details (date, unique identifying number or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and  (b) The date of initial diagnosis of systemic anaplastic large cell lymphoma; and  (c) Dates of commencement and completion of front-line curative intent chemotherapy; and  (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.  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 Authority Required procedures |
| C13184 | P13184 | CN13184 | Entrectinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND  Patient must have a WHO performance status of 2 or less; AND  Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; or  Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal; AND  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.  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).  The following must be documented in the patient's medical records  (a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material. | Compliance with Authority Required procedures |
| C13186 | P13186 | CN13186 | Crizotinib | 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 |
| C13205 | P13205 | CN13205 | Decitabine with cedazuridine | Chronic Myelomonocytic Leukaemia  Initial treatment  The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report; AND  The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.  No more than 3 cycles will be authorised under this restriction in a patient's lifetime.  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  (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  (b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority  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 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 | Compliance with Authority Required procedures |
| 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  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). | Compliance with Authority Required procedures |
| C13212 | P13212 | CN13212 | Brentuximab vedotin | 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 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  (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. | Compliance with Authority Required procedures |
| C13222 | P13222 | CN13222 | Nusinersen | 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  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. | Compliance with Written Authority Required procedures |
| C13230 | P13230 | CN13230 | Dapagliflozin  Empagliflozin | Chronic kidney disease  Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of:   (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND  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  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  Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND  Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13230 |
| C13231 | P13231 | CN13231 | Brentuximab vedotin | Relapsed or Refractory Hodgkin lymphoma  Continuing treatment  Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND  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 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 |
| C13233 | P13233 | CN13233 | Crizotinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND  Patient must have a WHO performance status of 2 or less;  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.  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).  The following must be documented in the patient's medical records  (a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material. | Compliance with Authority Required procedures |
| C13236 | P13236 | CN13236 | Vedolizumab | Severe Crohn disease  Balance of supply - subcutaneous form  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 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  Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; AND  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  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form. | Compliance with Authority Required procedures |
| C13237 | P13237 | CN13237 | Vedolizumab | Moderate to severe ulcerative colitis  Balance of supply - subcutaneous form  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 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  Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; AND  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  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form. | Compliance with Authority Required procedures |
| C13241 | P13241 | CN13241 | Decitabine with cedazuridine | Acute Myeloid Leukaemia  Initial treatment  The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination; AND  The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.  The following reports must be documented in the patient's medical records  (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and  (b) full blood examination report. | Compliance with Authority Required procedures |
| C13242 | P13242 | CN13242 | Gilteritinib | Relapsed or refractory Acute Myeloid Leukaemia  Continuing treatment  Patient must have previously received 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 not have developed disease progression while being treated with this drug for this condition; AND  Patient must not be undergoing or have undergone a stem cell transplant.  Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.  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.  Progressive disease is defined as the presence of any of the following  (a) Leukaemic cells in the CSF; or  (b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or  (c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or  (d) Extramedullary leukaemia. | Compliance with Authority Required procedures |
| C13246 | P13246 | CN13246 | Vorinostat | Cutaneous T-cell lymphoma  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 PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures |
| C13250 | P13250 | CN13250 | Crizotinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND  Patient must have a WHO performance status of 2 or less; AND  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  Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition. or  Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.  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).  The following must be documented in the patient's medical records  (a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material. | Compliance with Authority Required procedures |
| C13251 | P13251 | CN13251 | Crizotinib | 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 |
| 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  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.  (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. | Compliance with Written Authority Required procedures |
| 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.  Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations  (a) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR  (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  (c) 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR  (d) 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR  (e) Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.  Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations  (a) 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR  (b) 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.  The following information must be provided by the prescriber at the time of application  (a) The patient's International Prognostic Scoring System (IPSS) score.  The following reports must be documented in the patient's medical records  (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and  (b) full blood examination report; and  (c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).  No more than 3 cycles will be authorised under this restriction in a patient's lifetime. | Compliance with Authority Required procedures |
| C13268 | P13268 | CN13268 | Vismodegib | 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  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.  (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. | Compliance with Written Authority Required procedures |
| C13270 | P13270 | CN13270 | Nusinersen | Spinal muscular atrophy (SMA)  Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood  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 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;  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);  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 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  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) 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.  In this authority application, confirm  (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. | Compliance with Written Authority Required procedures |
| 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 1st percentile for age plus sex at the time treatment first commenced; AND  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; 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.  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  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. Recent growth data (height and weight, not 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.  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).  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. | Compliance with Authority Required procedures |
| C13284 | P13284 | CN13284 | Somatrogon | Short stature and slow growth  Initial treatment  Patient must have a current height at or below the 1st percentile for age and sex; AND  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; 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 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; AND  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  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  Must be treated by a specialist or consultant physician in paediatric endocrinology; or  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  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:  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.  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).  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. | Compliance with Authority Required procedures |
| C13287 | P13287 | CN13287 | Somatrogon | Short stature associated with biochemical growth hormone deficiency  Continuing treatment as a reclassified patient  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:   (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  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 at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  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  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  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  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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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.  Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.  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  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.  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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13288 | P13288 | CN13288 | Somatrogon  Somatropin | Short stature associated with biochemical growth hormone deficiency  Change of drug  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:   (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication; AND  Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; or  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  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:   (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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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 specialist or consultant physician in paediatric endocrinology; or  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  Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.  Definition  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  (a) the 50th percentile growth velocity for bone age;  (b) an increase in height standard deviation score for chronological age;  (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  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.  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  (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).  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. | Compliance with Authority Required procedures |
| C13290 | P13290 | CN13290 | Avelumab | 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  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13290 |
| C13292 | P13292 | CN13292 | Somatrogon | Short stature associated with biochemical growth hormone deficiency  Initial treatment  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  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  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  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  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  Patient must have a current height at or below the 1st percentile for age and sex; or  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; 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 specialist or consultant physician in paediatric endocrinology; or  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  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:  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  (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.  2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.  3. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations.  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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13293 | P13293 | CN13293 | Mecasermin | Severe growth failure with primary insulin-like growth factor-1 deficiency  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have a bone age of less than 13.5 years (females); or  Patient must have a bone age of less than 15.5 years (males); AND  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  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  The condition must be yet to respond to this drug treatment only for the reason of sub-optimal dosing; AND  Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; or  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.  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  (1) The patient's height (cm);  (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  (i) the most recently prescribed dose (mg/kg) that resulted in an inadequate response;  (ii) the dose (mg/kg) (between 0.04 to 0.12) that was/will be subsequently prescribed to address the inadequate response;  (3) The patient's weight (kg);  (4) The patient's growth velocity in response to the preceding supply of drug (cm/year; extrapolated for time on treatment);  (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.  Height, growth velocity and weight measurements must not be more than three months old at the time of application.  Document growth improvements 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 Authority Required procedures |
| C13294 | P13294 | CN13294 | Somatrogon | Short stature associated with biochemical growth hormone deficiency  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 problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  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  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  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  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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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.  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  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.  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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13297 | P13297 | CN13297 | Somatrogon | Short stature associated with biochemical growth hormone deficiency  Recommencement of treatment  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:   (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication; AND  Patient must have had a lapse in growth hormone treatment; AND  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:   (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 not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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  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.  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).  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. | Compliance with Authority Required procedures |
| C13298 | P13298 | CN13298 | Somatrogon | Short stature associated with biochemical growth hormone deficiency  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 at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  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  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  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  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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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.  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  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.  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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13304 | P13304 | CN13304 | Somatrogon | Short stature and slow growth  Recommencement of treatment  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:   (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication; AND  Patient must have had a lapse in growth hormone treatment; AND  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:   (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 not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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  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.  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).  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. | Compliance with Authority Required procedures |
| C13308 | P13308 | CN13308 | Somatrogon | Short stature and slow growth  Continuing treatment  Patient must be undergoing continuing PBS-subsidised therapy with this drug - subsidy through this treatment phase must not:   (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication; AND  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 achieved the 50th percentile growth velocity for bone age plus sex following the most recent supply; or  Patient must have achieved an increase in height standard deviation score for chronological age plus sex following the most recent supply; or  Patient must have achieved a minimum growth velocity of 4 cm per year following the most recent supply; or  Patient must have achieved a mid-parental height standard deviation score following the most recent supply; or  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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  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  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).  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).  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. | Compliance with Authority Required procedures |
| C13309 | P13309 | CN13309 | Somatrogon  Somatropin | Short stature and slow growth  Change of drug  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:   (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication; AND  Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; or  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  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:   (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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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 specialist or consultant physician in paediatric endocrinology; or  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  Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.  Definition  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  (a) the 50th percentile growth velocity for bone age;  (b) an increase in height standard deviation score for chronological age;  (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  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.  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  (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).  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. | Compliance with Authority Required procedures |
| C13311 | P13311 | CN13311 | Somatrogon | Short stature associated with biochemical growth hormone deficiency  Continuing treatment  Patient must be undergoing continuing PBS-subsidised therapy with this drug - subsidy through this treatment phase must not:   (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication; AND  Patient must have achieved the 50th percentile growth velocity for bone age plus sex following the most recent supply; or  Patient must have achieved an increase in height standard deviation score for chronological age plus sex following the most recent supply; or  Patient must have achieved a minimum growth velocity of 4 cm per year following the most recent supply; or  Patient must have achieved a mid-parental height standard deviation score following the most recent supply; or  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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.  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  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).  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).  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. | Compliance with Authority Required procedures |
| C13312 | P13312 | CN13312 | Somatrogon | Short stature and slow growth  Continuing treatment as a reclassified patient  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:   (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  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 1st percentile for age plus sex at the time treatment first commenced; AND  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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  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.  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).  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. | Compliance with Authority Required procedures |
| C13313 | P13313 | CN13313 | Avelumab | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13313 |
| C13318 | P13318 | CN13318 | Somatrogon | 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 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 1st percentile for age plus sex at the time treatment first commenced; AND  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; 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  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. 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 the patient has chronological age greater than 2.5 years.  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).  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. | Compliance with Authority Required procedures |
| C13320 | P13320 | CN13320 | Mecasermin | Severe growth failure with primary insulin-like growth factor-1 deficiency  Initial treatment  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:   (i) age, (ii) gender; AND  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 any time prior to initiating treatment with this drug) being at least 3 standard deviations below the norm, adjusted for each of:   (i) age, (ii) gender; AND  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  The condition must not be caused by growth hormone deficiency; AND  Patient must have a bone age of less than 13.5 years (females); or  Patient must have a bone age of less than 15.5 years (males); AND  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:   (i) malnutrition, (ii) hypopituitarism, (iii) hypothyroidism, (iv) medication side effects; AND  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  Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; or  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.  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 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  (1) Insulin-like growth factor-1 deficiency  (2) Short stature  (3) Normal growth hormone levels  (4) Bone age (where the patient has a chronological age of at least 2.5 years):  (5) The patient's weight (kg);  (6) The prescribed dose (mg/kg) (between 0.04 to 0.12);  (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.  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;  (2) Short stature  (3) Normal growth hormone levels  (4) Bone age (where the patient has a chronological age of at least 2.5 years):  (5) The patient's weight (kg);  (6) The prescribed dose (mg/kg) (between 0.04 to 0.12);  (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.  State the patient's height (cm);  (3) Normal growth hormone levels  (4) Bone age (where the patient has a chronological age of at least 2.5 years):  (5) The patient's weight (kg);  (6) The prescribed dose (mg/kg) (between 0.04 to 0.12);  (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.  State the patient's most recent growth hormone level measurement (mcg/L) - this figure must be greater than 6.6 mcg/L;  (4) Bone age (where the patient has a chronological age of at least 2.5 years):  (5) The patient's weight (kg);  (6) The prescribed dose (mg/kg) (between 0.04 to 0.12);  (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.  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;  (5) The patient's weight (kg);  (6) The prescribed dose (mg/kg) (between 0.04 to 0.12);  (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.  Height, growth velocity and weight measurements must not be more than three months old at the time of application.  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 Authority Required procedures |
| C13321 | P13321 | CN13321 | Trientine | Chelation of elevated copper levels  Patient must have a diagnosis of Wilson disease; AND  Patient must be intolerant to penicillamine; AND  Must be treated by a specialist medical practitioner, where this authority application is to initiate treatment with this drug, of the following type:   (i) gastroenterologist, (ii) hepatologist, (iii) neurologist; the authority prescription must be completed by the specialist prescriber. or  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  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.  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.  Document what these findings were in the patient's medical records. Do not supply them in this authority application.  Refer to the following definitions if in doubt over what constitutes an acceptable intolerance to penicillamine  Side effects of penicillamine occurring soon after initiation (within first few weeks/months)  (i) fever, (ii) rash, (iii) enlarged lymph nodes, (iv) neutropenia, (v) thrombocytopenia, (vi) proteinuria, (vii) severe, persistent nausea.  (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 thromobocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia.  Side effects of penicillamine developing later  (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 thromobocytopenia/leukopenia, (xiii) lupus-like syndrome (haematuria, proteinuria, positive antinuclear antibody), (xiv) arthralgia.  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. | Compliance with Authority Required procedures |
| C13322 | P13322 | CN13322 | Cemiplimab | Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have received non-PBS-subsidised therapy with this drug for this condition prior to 1 November 2022; AND  The condition must be unsuitable for each of:   (i) curative surgical resection, (ii) curative radiotherapy; AND  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  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first:   (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. | Compliance with Authority Required procedures |
| C13327 | P13327 | CN13327 | Eltrombopag | Severe thrombocytopenia  Second or Subsequent Continuing treatment  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  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  Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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. | Compliance with Authority Required procedures |
| C13330 | P13330 | CN13330 | Burosumab | X-linked hypophosphataemia  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  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. | Compliance with Authority Required procedures |
| C13336 | P13336 | CN13336 | Aflibercept  Dexamethasone  Ranibizumab | Central retinal vein occlusion with macular oedema  Continuing treatment  Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13336 |
| C13337 | P13337 | CN13337 | Aflibercept  Ranibizumab | 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 pathologic myopia (PM); 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. | Compliance with Written Authority Required procedures |
| 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  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  (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. | Compliance with Written Authority Required procedures |
| C13346 | P13346 | CN13346 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Initial treatment  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  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  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  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  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  Patient must have a current height at or below the 1st percentile for age and sex; or  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; 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 specialist or consultant physician in paediatric endocrinology; or  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  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 the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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  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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13350 | P13350 | CN13350 | Somatropin | Short stature and slow growth  Continuing 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 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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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; 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).  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. | Compliance with Authority Required procedures |
| C13352 | P13352 | CN13352 | Somatropin | 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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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.  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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 (except for a patient whose chronological age is 2.5 years or less); 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).  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. | Compliance with Authority Required procedures |
| C13353 | P13353 | CN13353 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Recommencement of treatment as a reclassified patient  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  Patient must have had a lapse in 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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  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  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  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  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  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  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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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 recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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  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 16 weeks' worth of treatment (with up to 1 repeat allowed).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13355 | P13355 | CN13355 | Somatropin | Short stature and slow growth  Recommencement of treatment as a reclassified patient  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  Patient must have had a lapse in 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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  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  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  Patient must have had both:   (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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; 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 recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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 (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. Recent growth data (height and weight, not older than three months); AND  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  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).  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. | Compliance with Authority Required procedures |
| C13356 | P13356 | CN13356 | Somatropin | Short stature and slow growth  Initial treatment  Patient must have a current height at or below the 1st percentile for age and sex; AND  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; 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 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; AND  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  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  Must be treated by a specialist or consultant physician in paediatric endocrinology; or  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  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 the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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  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  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).  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. | Compliance with Authority Required procedures |
| C13359 | P13359 | CN13359 | Somatropin | Short stature and slow growth  Continuing treatment as a reclassified patient  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  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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  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  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  Patient must have had both:   (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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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.  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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 (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  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  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).  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. | Compliance with Authority Required procedures |
| C13360 | P13360 | CN13360 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Recommencement of 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 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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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.  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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 (except for a patient whose chronological age is 2.5 years or less); 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).  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. | Compliance with Authority Required procedures |
| C13363 | P13363 | CN13363 | 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/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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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; 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).  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. | Compliance with Authority Required procedures |
| C13364 | P13364 | CN13364 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Continuing treatment as a reclassified patient  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  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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  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  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  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  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  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  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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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  (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. 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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13367 | P13367 | CN13367 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Initial treatment  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  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  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  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  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  Patient must have a current height at or below the 1st percentile for age and sex; or  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; 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 specialist or consultant physician in paediatric endocrinology; or  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  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 the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13368 | P13368 | CN13368 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Recommencement of 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 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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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.  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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).  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. | Compliance with Authority Required procedures |
| C13377 | P13377 | CN13377 | Burosumab | X-linked hypophosphataemia  Initial treatment - New patient  Patient must have a documented confirmation of PHEX pathogenic variant; or  Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following:   (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  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.  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. | Compliance with Authority Required procedures |
| C13378 | P13378 | CN13378 | Nintedanib  Pirfenidone | 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  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  The treatment must be the sole PBS-subsidised therapy for this condition; AND  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  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  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following:   (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.  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.  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.  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  (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 Written Authority Required procedures |
| C13380 | P13380 | CN13380 | Nintedanib  Pirfenidone | Idiopathic pulmonary fibrosis  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  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  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  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| C13381 | P13381 | CN13381 | Nintedanib  Pirfenidone | Idiopathic pulmonary fibrosis  Initial treatment 2 - change or recommencement of treatment  Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  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  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  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| C13384 | P13384 | CN13384 | Aflibercept  Ranibizumab | Branch 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 branched retinal vein occlusion (BRVO); AND  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  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. | Compliance with Written Authority Required procedures |
| C13387 | P13387 | CN13387 | Aflibercept  Dexamethasone  Ranibizumab | Branch retinal vein occlusion with macular oedema  Continuing treatment  Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13387 |
| C13388 | P13388 | CN13388 | Aflibercept  Faricimab  Ranibizumab | 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  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  (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. | Compliance with Written Authority Required procedures |
| C13390 | P13390 | CN13390 | Aflibercept  Ranibizumab | 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  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. | Compliance with Written Authority Required procedures |
| C13392 | P13392 | CN13392 | Aflibercept  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 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. | Compliance with Authority Required procedures - 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/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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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; 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; 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).  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. | Compliance with Authority Required procedures |
| C13396 | P13396 | CN13396 | Romiplostim | Severe thrombocytopenia  Second or Subsequent Continuing treatment  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  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  Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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.  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.  Authority approval will not be given for doses higher than 10 micrograms/kg/week | Compliance with Authority Required procedures |
| C13400 | P13400 | CN13400 | Burosumab | X-linked hypophosphataemia  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  Patient must have a documented confirmation of PHEX pathogenic variant; or  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:   (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  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. | Compliance with Authority Required procedures |
| C13401 | P13401 | CN13401 | Nintedanib | 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 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  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 that is both:   (i) at least 30% predicted, (ii) no greater than 80% predicted; AND  The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is); AND  The condition must not be due to reversible causes (e.g. drug toxicity); AND  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  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  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND  Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following:   (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.  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  (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)  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.  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. | Compliance with Written Authority Required procedures |
| C13402 | P13402 | CN13402 | Aflibercept  Faricimab  Ranibizumab | Diabetic macular oedema (DMO)  Continuing treatment  Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13402 |
| C13406 | P13406 | CN13406 | Aflibercept  Faricimab  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 be due to age-related macular degeneration (AMD); 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 13406 |
| C13411 | P13411 | CN13411 | Cemiplimab | Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)  Continuing treatment  Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first:   (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. | Compliance with Authority Required procedures |
| C13412 | P13412 | CN13412 | Nintedanib | Progressive fibrosing Interstitial lung disease  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  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  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  Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications:   (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| C13417 | P13417 | CN13417 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Continuing treatment as a reclassified patient  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  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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  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  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  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  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  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  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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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 *National Health (Growth Hormone Program) Special Arrangement 2015* 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  (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. 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; 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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13418 | P13418 | CN13418 | Somatropin | Short stature associated with biochemical growth hormone deficiency  Recommencement of treatment as a reclassified patient  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  Patient must have had a lapse in 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 treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; 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 non-compliance due to social/family problems; AND  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  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  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  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  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  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  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  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  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  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  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  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 recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* 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).  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 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  6. A bone age result performed within the last 12 months; AND  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).  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.  Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.  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. | Compliance with Authority Required procedures |
| C13419 | P13419 | CN13419 | Cemiplimab | Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)  Initial treatment covering the first 3 treatment cycles  The condition must be unsuitable for each of:   (i) curative surgical resection, (ii) curative radiotherapy; AND  Patient must have had a WHO performance status of 0 or 1; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures |
| C13422 | P13422 | CN13422 | Ranibizumab | 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  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. | Compliance with Written Authority Required procedures |
| C13423 | P13423 | CN13423 | Dexamethasone | 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  Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; or  Patient must have failed prior treatment with VEGF inhibitors; 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. | Compliance with Written Authority Required procedures |
| C13424 | P13424 | CN13424 | Aflibercept  Faricimab | 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  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. | Compliance with Written Authority Required procedures |
| C13426 | P13426 | CN13426 | Brolucizumab | 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 be due to age-related macular degeneration (AMD); 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 |
| C13427 | P13427 | CN13427 | Ranibizumab | 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 not be due to pathologic myopia; AND  The condition must not be due to age-related macular degeneration; 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. | Compliance with Written Authority Required procedures |
| C13428 | P13428 | CN13428 | Dexamethasone | Diabetic macular oedema (DMO)  Continuing treatment  Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; 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 previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13428 |
| C13429 | P13429 | CN13429 | Dexamethasone | Branch 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 branched retinal vein occlusion (BRVO); AND  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  The condition must be diagnosed by optical coherence tomography; or  The condition must be diagnosed by fluorescein angiography; AND  Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; or  Patient must have failed prior treatment with VEGF inhibitors; 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. | Compliance with Written Authority Required procedures |
| C13431 | P13431 | CN13431 | Pembrolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment - 3 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 7 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 13431 |
| C13432 | P13432 | CN13432 | Pembrolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing treatment - 3 weekly treatment regimen  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 not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first. | Compliance with Authority Required procedures - Streamlined Authority Code 13432 |
| C13433 | P13433 | CN13433 | Nivolumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial combination treatment (with ipilimumab) as first-line drug therapy  The condition must be 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 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 be in combination with platinum-based chemotherapy for the first two cycles; AND  The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 13433 |
| C13434 | P13434 | CN13434 | Tepotinib | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13434 |
| C13435 | P13435 | CN13435 | Tepotinib | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13435 |
| C13436 | P13436 | CN13436 | Pembrolizumab | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13436 |
| C13437 | P13437 | CN13437 | Pembrolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing treatment - 6 weekly treatment regimen  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 not exceed a total of 18 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first. | Compliance with Authority Required procedures - Streamlined Authority Code 13437 |
| C13441 | P13441 | CN13441 | Tepotinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13441 |
| C13442 | P13442 | CN13442 | Atezolizumab | Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)  1,200 mg administered once every 3 weeks  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13442 |
| C13443 | P13443 | CN13443 | Atezolizumab | Locally advanced or metastatic non-small cell lung cancer  Initial treatment - 3 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 non-small cell lung cancer; AND  Patient must have a WHO performance status of 0 or 1; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer 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 13443 |
| C13445 | P13445 | CN13445 | Nivolumab | Locally advanced or metastatic non-small cell lung cancer  Initial treatment as second-line drug therapy  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 treatment must be the sole PBS-subsidised systemic anti-cancer 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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13445 |
| 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13451 |
| C13458 | P13458 | CN13458 | Eculizumab | 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  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. | Compliance with Authority Required procedures |
| C13459 | P13459 | CN13459 | Eculizumab  Ravulizumab | 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).  For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the*'*Subsequent Continuing Treatment' criteria. | Compliance with Authority Required procedures |
| C13464 | P13464 | CN13464 | Eculizumab | 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  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  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  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, 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) must be at least 1.5 | Compliance with Authority Required procedures |
| C13469 | P13469 | CN13469 | Evolocumab | Familial homozygous hypercholesterolaemia  Initial treatment  The treatment must be in conjunction with dietary therapy and exercise; AND  The condition must have been confirmed by genetic testing; or  The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7; AND  Patient must have an LDL cholesterol level in excess of 1.8 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  Must be treated by a specialist physician. or  Must be treated by a physician who has consulted a specialist physician.  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.  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.  The following must be stated at the time of application and documented in the patient's medical records  (i) the qualifying Dutch Lipid Clinic Network Score; or  (ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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 dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or  (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information | Compliance with Authority Required procedures |
| C13482 | P13482 | CN13482 | Sildenafil  Tadalafil | Pulmonary arterial hypertension (PAH)  Initial 2 (change)  Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III 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, irrespective of the severity of their disease at the time the application to swap therapy is submitted.  Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.  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.  A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| C13484 | P13484 | CN13484 | Sildenafil  Tadalafil | 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  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 have WHO Functional Class II PAH, or WHO Functional Class III 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  (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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  The test results must not be more than 6 months old at the time of application.  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.  A maximum of 5 repeats may be requested. | Compliance with Written Authority Required procedures |
| C13491 | P13491 | CN13491 | Epoprostenol  Iloprost | Pulmonary arterial hypertension (PAH)  Initial 2 (change)  Patient must have documented 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, irrespective of the severity of their disease at the time the application to swap therapy is submitted.  Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.  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.  A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| C13492 | P13492 | CN13492 | Epoprostenol  Iloprost | 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 prostanoid, 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:   (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above; 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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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. | Compliance with Authority Required procedures |
| C13495 | P13495 | CN13495 | Bosentan | 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, irrespective of the severity of their disease at the time the application to swap therapy is submitted.  Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.  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.  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.  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. | Compliance with Authority Required procedures |
| C13496 | P13496 | CN13496 | Ambrisentan  Bosentan  Macitentan | Pulmonary arterial hypertension (PAH)  Initial 1 - 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 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 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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  The test results must not be more than 6 months old at the time of application. | Compliance with Written Authority Required procedures |
| C13497 | P13497 | CN13497 | Ambrisentan  Bosentan  Macitentan | Pulmonary arterial hypertension (PAH)  Initial 3 - changing to this drug in combination therapy (dual or triple therapy)  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 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. | Compliance with Authority Required procedures |
| C13499 | P13499 | CN13499 | Ambrisentan  Bosentan  Macitentan | 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. | Compliance with Authority Required procedures |
| C13500 | P13500 | CN13500 | Ambrisentan  Macitentan | 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.  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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  The test results must not be more than 6 months old at the time of application.  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.  A maximum of 5 repeats may be requested. | Compliance with Written Authority Required procedures |
| C13502 | P13502 | CN13502 | Riociguat | 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.  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.  A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| C13505 | P13505 | CN13505 | Epoprostenol  Iloprost | Pulmonary arterial hypertension (PAH)  Initial 3 - changing to this drug in combination therapy (dual or triple therapy)  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; 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; 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 |
| C13506 | P13506 | CN13506 | Epoprostenol  Iloprost | 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 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; 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; 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 |
| C13510 | P13510 | CN13510 | Epoprostenol  Iloprost | 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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  The test results must not be more than 6 months old at the time of application. | Compliance with Written Authority Required procedures |
| C13512 | P13512 | CN13512 | Epoprostenol | 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).  (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  The test results must not be more than 6 months old at the time of application.  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.  A maximum of 5 repeats may be requested. | Compliance with Written Authority Required procedures |
| C13514 | P13514 | CN13514 | Riociguat | Pulmonary arterial hypertension (PAH)  Initial 2 (change)  Patient must have documented 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.  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, irrespective of the severity of their disease at the time the application to swap therapy is submitted.  Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.  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.  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. | Compliance with Authority Required procedures |
| C13515 | P13515 | CN13515 | Riociguat | 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  (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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  The test results must not be more than 6 months old at the time of application.  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.  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. | Compliance with Written Authority Required procedures |
| C13518 | P13518 | CN13518 | Infliximab | Severe psoriatic 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 psoriatic arthritis; 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 to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND  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  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  Patient must not receive more than 22 weeks of treatment under this restriction;  Patient must be at least 18 years of age.  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.  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.  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  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  (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 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).  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.  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  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13526 | P13526 | CN13526 | Infliximab | 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  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  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  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  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  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  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.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and  (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and  (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and  (iv) the date of the most recent clinical assessment.  Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following  (a) patient must have evidence of intestinal inflammation;  (b) patient must be assessed clinically as being in a high faecal output state;  (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.  (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.  Evidence of intestinal inflammation includes  (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.  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  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.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website.  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.  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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13532 | P13532 | CN13532 | Etanercept | Severe psoriatic 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 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  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  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  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 psoriatic arthritis.  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.  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.  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  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  (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 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).  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.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13533 | P13533 | CN13533 | Etanercept | Severe psoriatic arthritis  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, 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 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 psoriatic arthritis.  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).  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13538 | P13538 | CN13538 | Etanercept | 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 continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.  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. | Compliance with Written Authority Required procedures |
| C13556 | P13556 | CN13556 | Adalimumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (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 be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; 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, and the face, hand, foot area diagrams 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.  The PASI assessment for 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. | Compliance with Written Authority Required procedures |
| C13558 | P13558 | CN13558 | Lorlatinib | 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 PBS indication; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C13560 | P13560 | CN13560 | Eculizumab | Paroxysmal nocturnal haemoglobinuria (PNH)  Initial treatment - initial 1 (new patient) induction doses  Patient must not have received prior treatment with this drug for this condition; AND  Patient must have a diagnosis of PNH established by flow cytometry; AND  Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND  Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND  Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; or  Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; 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; 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; 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; 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; or  Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; 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, 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) must be at least 1.5 | Compliance with Authority Required procedures |
| 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  Patient must have a documented left ventricular ejection fraction (LVEF) of less than 45%; AND  The condition must be stabilised following a decompensation event that required at least one of:   (i) hospitalisation in the past 6 months, (ii) intravenous diuretic therapy in the past three months; AND  Patient must not have clinical signs of fluid overload; AND  Patient must not have received intravenous treatment for fluid overload in the previous 24 hours; AND  Patient must not have a systolic blood pressure less than 100 mmHg; 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 |
| C13569 | P13569 | CN13569 | Sildenafil  Tadalafil | Pulmonary arterial hypertension (PAH)  Initial 3 - changing to this drug in combination therapy (dual or triple therapy)  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 prostanoid, (ii) one phosphodiesterase-5 inhibitor; 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  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  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 |
| C13570 | P13570 | CN13570 | Sildenafil  Tadalafil | 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 prostanoid, (ii) one phosphodiesterase-5 inhibitor; 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  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. | Compliance with Authority Required procedures |
| C13571 | P13571 | CN13571 | Bosentan | 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.  A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| C13572 | P13572 | CN13572 | Sildenafil  Tadalafil | 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.  A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| C13573 | P13573 | CN13573 | Sildenafil  Tadalafil | 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 prostanoid, (ii) one phosphodiesterase-5 inhibitor; 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 |
| C13575 | P13575 | CN13575 | Ambrisentan  Macitentan | 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.  A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| C13576 | P13576 | CN13576 | Ambrisentan  Macitentan | 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, irrespective of the severity of their disease at the time the application to swap therapy is submitted.  Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.  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.  A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| C13577 | P13577 | CN13577 | Epoprostenol  Iloprost | 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.  A maximum of 5 repeats may be requested. | Compliance with Authority Required procedures |
| C13580 | P13580 | CN13580 | Ambrisentan  Bosentan  Macitentan | 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 prostanoid, 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:   (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above; 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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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. | Compliance with Authority Required procedures |
| 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  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 an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  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  Patient must not receive more than 22 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 one month old at the time of initial application.  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.  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.  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  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13586 | P13586 | CN13586 | Infliximab | 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 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. | Compliance with Written Authority Required procedures |
| C13587 | P13587 | CN13587 | Infliximab | 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  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 be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  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 and face, hand, foot area diagrams 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.  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. | Compliance with Written Authority Required procedures |
| C13593 | P13593 | CN13593 | Etanercept | 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  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 an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  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  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 one month old at the time of initial application.  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.  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.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13598 | P13598 | CN13598 | Etanercept | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (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 16 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.  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.  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.  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 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.  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 following  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C13599 | P13599 | CN13599 | Adalimumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  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  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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  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  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13602 | P13602 | CN13602 | Adalimumab | 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  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  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  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  Patient must not receive more than 16 weeks of treatment under this restriction; AND  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  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  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.  The authority application must be made in writing and must include  (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).  Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following  (a) patient must have evidence of intestinal inflammation;  (b) patient must be assessed clinically as being in a high faecal output state;  (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.  (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.  Evidence of intestinal inflammation includes  (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.  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.  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.  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.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website.  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.  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 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. | Compliance with Written Authority Required procedures |
| C13609 | P13609 | CN13609 | Adalimumab | 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  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.  The authority application must be made in writing and must include  (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).  Evidence of intestinal inflammation includes  (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.  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.  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.  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 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. | Compliance with Written Authority Required procedures |
| C13612 | P13612 | CN13612 | Adalimumab | 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 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. | Compliance with Written Authority Required procedures |
| C13616 | P13616 | CN13616 | Pegcetacoplan | 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)  (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) | Compliance with Authority Required procedures |
| C13621 | P13621 | CN13621 | Vericiguat | Chronic heart failure  Grandfather 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 have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2022; AND  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  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  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:   (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  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  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  Patient must not have a systolic blood pressure less than 100 mmHg; 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 |
| C13624 | P13624 | CN13624 | Leuprorelin | 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. |  |
| C13625 | P13625 | CN13625 | Natalizumab | 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.  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.  Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.  For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 13625 |
| C13629 | P13629 | CN13629 | Sildenafil  Tadalafil | Pulmonary arterial hypertension (PAH)  Initial 1 - 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 endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; or  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 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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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. | Compliance with Authority Required procedures |
| C13631 | P13631 | CN13631 | Iloprost | 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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  The test results must not be more than 6 months old at the time of application.  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.  A maximum of 5 repeats may be requested. | Compliance with Written Authority Required procedures |
| C13632 | P13632 | CN13632 | Bosentan | 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  (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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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 the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.  (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.  The test results must not be more than 6 months old at the time of application.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13634 | P13634 | CN13634 | Epoprostenol  Iloprost | 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 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 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 |
| C13639 | P13639 | CN13639 | Infliximab | 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  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  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 at least 18 years of age.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and  (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and  (iii) the date of the most recent clinical assessment.  Evidence of intestinal inflammation includes  (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.  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.  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.  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.  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 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. | Compliance with Written Authority Required procedures |
| C13640 | P13640 | CN13640 | Infliximab | 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).  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  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13641 | P13641 | CN13641 | Infliximab | Complex refractory Fistulising Crohn disease  Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1)  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 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  Patient must have an externally draining enterocutaneous or rectovaginal fistula.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following  (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition.  The most recent fistula assessment must be no more than 1 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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13646 | P13646 | CN13646 | Etanercept | 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 16 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.  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.  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 with this drug for this condition. Demonstration of response should be provided within this timeframe.  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.  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 following  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C13647 | P13647 | CN13647 | Etanercept | 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  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 be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; 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 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. | Compliance with Written Authority Required procedures |
| C13650 | P13650 | CN13650 | Adalimumab | Severe psoriatic 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 psoriatic arthritis; 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 to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND  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  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  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be at least 18 years of age.  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.  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.  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  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  (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 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).  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. 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 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 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 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. | Compliance with Written Authority Required procedures |
| C13655 | P13655 | CN13655 | Pegcetacoplan | Paroxysmal nocturnal haemoglobinuria (PNH)  Initial treatment (new patient)  Patient must not have received prior treatment with this drug for this condition; AND  Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months; AND  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  Patient must be intolerant to C5 inhibitors as determined by the treating physician; AND  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  The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy; 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.  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) | Compliance with Authority Required procedures |
| C13658 | P13658 | CN13658 | Pegcetacoplan | 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  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  Patient must be intolerant to C5 inhibitors as determined by the treating physician prior to initiating non-PBS-subsidised treatment with this drug; AND  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  The treatment must not be in combination with a Complement 5 (C5) inhibitor; AND  Patient must have had at least the initial 4 weeks of pegcetacoplan treatment; 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  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)  (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) | Compliance with Authority Required procedures |
| 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 of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing 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 commencing 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 commencing treatment with eculizumab; 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, 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) must be at least 1.5 | Compliance with Authority Required procedures |
| C13661 | P13661 | CN13661 | Eculizumab | Paroxysmal nocturnal haemoglobinuria (PNH)  Subsequent Continuing Treatment  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). | Compliance with Authority Required procedures |
| C13671 | P13671 | CN13671 | Sildenafil  Tadalafil | 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:   (i) classed as at least Class III PAH, (ii) untreated with any drug from the drug classes mentioned above; 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  (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.  (2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted  (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.  - RHC composite assessment; and  - ECHO composite assessment; and  - 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  - RHC plus ECHO composite assessments;  - RHC composite assessment plus 6MWT;  - RHC composite assessment only.  In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is  - 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. | Compliance with Authority Required procedures |
| C13681 | P13681 | CN13681 | Adalimumab | 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 and one of which must be:   (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  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:   (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  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 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  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 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.  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.  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.  The following criteria indicate failure to achieve an adequate response 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 or a C-reactive protein (CRP) level greater than 15 mg per L; AND either  (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  (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 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.  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.  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 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 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. | Compliance with Written Authority Required procedures |
| C13684 | P13684 | CN13684 | Eculizumab | Paroxysmal nocturnal haemoglobinuria (PNH)  Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)  Patient must be planning pregnancy; or  Patient must be pregnant; AND  Patient must have received PBS-subsidised treatment with ravulizumab for this condition; 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).  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. | Compliance with Authority Required procedures |
| C13691 | P13691 | CN13691 | Infliximab | Moderate to 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)]; 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.  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.  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. | Compliance with Authority Required procedures |
| C13692 | P13692 | CN13692 | Infliximab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement 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 22 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 the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  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 following  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C13694 | P13694 | CN13694 | Adalimumab | 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  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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  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  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 above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  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.  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 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.  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 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. | Compliance with Written Authority Required procedures |
| C13702 | P13702 | CN13702 | Infliximab | Moderate to 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)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; 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 failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:   (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 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  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  Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment; 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; and  (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.  The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.  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.  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.  Details of the accepted toxicities including severity can be found on the Department of Human Services website.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C13710 | P13710 | CN13710 | Pegcetacoplan | Paroxysmal nocturnal haemoglobinuria (PNH)  Return from PBS-subsidised eculizumab post pregnancy or from PBS-subsidised Complement 5 (C5) inhibitor for reasons other than post pregnancy  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 3 (switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)' criteria; or  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  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 be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy; 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.  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. | Compliance with Authority Required procedures |
| C13716 | P13716 | CN13716 | Lorlatinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND  Patient must have a WHO performance status of 2 or less;  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. | Compliance with Authority Required procedures |
| C13718 | P13718 | CN13718 | Natalizumab | 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.  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.  Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.  For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 13718 |
| C13719 | P13719 | CN13719 | Infliximab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement 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 22 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.  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.  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.  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 following  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C13726 | P13726 | CN13726 | Pembrolizumab | Relapsed or Refractory Hodgkin lymphoma  Initial treatment  Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; or  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; AND  Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13726 |
| C13727 | P13727 | CN13727 | Pembrolizumab | Relapsed or refractory primary mediastinal B-cell lymphoma  Initial treatment  The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of:   (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan; AND  Patient must have been treated with rituximab-based chemotherapy for this condition; AND  Patient must be experiencing relapsed/refractory disease; AND  Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; or  Patient must have undergone an autologous stem cell transplant (ASCT); or  Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy; 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 this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13727 |
| C13728 | P13728 | CN13728 | Pembrolizumab | Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer  Initial treatment  Patient must be untreated for this PBS indication (i.e untreated for each of:   (i) unresectable disease, (ii) metastatic disease); AND  Patient must not have received prior treatment for colorectal cancer with each of:   (i) a programmed cell death-1 (PD-1) inhibitor, (ii) a programmed cell death ligand-1 (PD-L1) inhibitor; AND  Patient must have a WHO performance status of 0 or 1; AND  Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test; 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. | Compliance with Authority Required procedures |
| C13730 | P13730 | CN13730 | Pembrolizumab | Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; 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; AND  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. | Compliance with Authority Required procedures |
| C13731 | P13731 | CN13731 | Pembrolizumab | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx  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  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; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13731 |
| C13732 | P13732 | CN13732 | Pembrolizumab | Relapsed or refractory primary mediastinal B-cell lymphoma  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 PBS-subsidised treatment with this drug for this condition; 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; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13732 |
| C13735 | P13735 | CN13735 | Pembrolizumab | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx  Initial treatment  The condition must be incurable by local therapies in the locally advanced setting; AND  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  Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if previously treated in the locally advanced setting; AND  Patient must have had a WHO performance status of 0 or 1; AND  The treatment must be either:   (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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13735 |
| C13736 | P13736 | CN13736 | Pembrolizumab | Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer  Continuing treatment  Patient must have previously received 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 not have developed disease progression while being treated with this drug for this condition; 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; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13736 |
| C13739 | P13739 | CN13739 | Pembrolizumab | Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer  Initial treatment  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 on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; or  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  Patient must have a WHO performance status of 2 or less; 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 this condition; 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13739 |
| C13741 | P13741 | CN13741 | Pembrolizumab | Relapsed or Refractory Hodgkin lymphoma  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 PBS-subsidised treatment with this drug for this condition; 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; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13741 |
| C13743 | P13743 | CN13743 | Pegcetacoplan | Paroxysmal nocturnal haemoglobinuria (PNH)  Subsequent continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' 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 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. | Compliance with Authority Required procedures |
| C13745 | P13745 | CN13745 | Bortezomib | Newly diagnosed systemic light chain amyloidosis  Administration on Days 1, 8, 15 and 22 of six treatment cycles (28 days per cycle) in total  Patient must be undergoing concurrent treatment with PBS-subsidised daratumumab for this PBS indication. |  |
| C13746 | P13746 | CN13746 | Pomalidomide | Multiple myeloma  Initial treatment - dual therapy in combination with dexamethasone  The treatment must form part of dual combination therapy limited to:   (i) this drug, (ii) dexamethasone; AND  Patient must have undergone or be ineligible for a primary stem cell transplant; AND  Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information; AND  Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.  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.  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.  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  (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  (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.  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 |
| C13748 | P13748 | CN13748 | Nirmatrelvir and ritonavir | SARS-CoV-2 infection  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:   (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.  For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions  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.  Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.  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.  Access to this drug through this restriction is permitted irrespective of vaccination status.  Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.  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.  This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | Compliance with Authority Required procedures - Streamlined Authority Code 13748 |
| C13752 | P13752 | CN13752 | Daratumumab | Relapsed and/or refractory multiple myeloma  Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)  The condition must be confirmed by a histological diagnosis; AND  The treatment must be in combination with bortezomib and dexamethasone; AND  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  Patient must be undergoing treatment with this drug in one of the following situations:   (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.  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.  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.  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  (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; 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 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.  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.  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, 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. | Compliance with Authority Required procedures |
| C13753 | P13753 | CN13753 | Leflunomide | Severe active rheumatoid arthritis  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. |  |
| C13755 | P13755 | CN13755 | Pomalidomide | Multiple myeloma  Continuing treatment - dual therapy in combination with dexamethasone  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  The treatment must form part of dual combination therapy limited to:   (i) this drug, (ii) dexamethasone.  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). | Compliance with Authority Required procedures |
| C13757 | P13757 | CN13757 | Pomalidomide | Multiple myeloma  Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)  The condition must be confirmed by a histological diagnosis; AND  The treatment must form part of triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND  Patient must have progressive disease after at least one prior therapy that is either:   (i) lenalidomide monotherapy, (ii) contains lenalidomide; AND  Patient must have undergone or be ineligible for a stem cell transplant.  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. | Compliance with Authority Required procedures |
| C13759 | P13759 | CN13759 | Nirmatrelvir and ritonavir | SARS-CoV-2 infection  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 not require hospitalisation for COVID-19 infection at the time of prescribing; AND  The treatment must be initiated within 5 days of symptom onset; or  The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic;  Patient must be at least 70 years of age.  Access to this drug through this restriction is permitted irrespective of vaccination status.  Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.  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.  This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | Compliance with Authority Required procedures - Streamlined Authority Code 13759 |
| C13762 | P13762 | CN13762 | Faricimab | Subfoveal choroidal neovascularisation (CNV)  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  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  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. | Compliance with Written Authority Required procedures |
| C13768 | P13768 | CN13768 | Pomalidomide | Multiple myeloma  Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must form part of triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND  Patient must not have developed disease progression while receiving PBS-subsidised 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. | Compliance with Authority Required procedures |
| C13769 | P13769 | CN13769 | Brolucizumab | 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. | Compliance with Written Authority Required procedures |
| C13770 | P13770 | CN13770 | Faricimab | 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. | Compliance with Written Authority Required procedures |
| C13771 | P13771 | CN13771 | Leflunomide | Severe active psoriatic arthritis  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. |  |
| C13774 | P13774 | CN13774 | Daratumumab | Newly diagnosed systemic light chain amyloidosis  Continuing treatment from week 25 onwards (administered once every four weeks)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  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  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. | Compliance with Authority Required procedures |
| C13782 | P13782 | CN13782 | Lenalidomide | Relapsed and/or refractory multiple myeloma  Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone  Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS; AND  Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing. | Compliance with Authority Required procedures |
| C13785 | P13785 | CN13785 | Lenalidomide | Multiple myeloma  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  The condition must be newly diagnosed; AND  The condition must be confirmed by a histological diagnosis; AND  The treatment must form part of triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND  Patient must not have been treated with lenalidomide or bortezomib for this condition; AND  The treatment must not exceed a total of 4 cycles 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  (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.  (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.  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  (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 |
| C13786 | P13786 | CN13786 | Lenalidomide | Multiple myeloma  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  The condition must be newly diagnosed; AND  The condition must be confirmed by a histological diagnosis; AND  The treatment must form part of triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND  Patient must not have been treated with lenalidomide or bortezomib for this condition; AND  The treatment must not exceed a total of 4 cycles 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  (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.  (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.  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  (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 |
| C13787 | P13787 | CN13787 | Lenalidomide | Multiple myeloma  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  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  The treatment must form part of dual combination therapy limited to:   (i) this drug, (ii) dexamethasone.  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. | Compliance with Authority Required procedures |
| C13791 | P13791 | CN13791 | Lenalidomide | Multiple myeloma  Initial treatment with lenalidomide monotherapy in newly diagnosed disease  The treatment must be as monotherapy; AND  The condition must be confirmed by a histological diagnosis; AND  Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma; AND  Patient must not have progressive disease following autologous stem cell transplant (ASCT).  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  (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and  (2) the date the autologous stem cell transplant was performed; and  (3) nomination of which disease activity parameters will be used to assess progression.  (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.  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  (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 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). | Compliance with Written Authority Required procedures |
| C13801 | P13801 | CN13801 | Lenalidomide | 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 mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.  The following evidence of response must be provided at each application  (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;  All reports must be documented in the patient's medical records.  For first continuing applications, 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). | Compliance with Authority Required procedures |
| C13803 | P13803 | CN13803 | Lenalidomide | Multiple myeloma  Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease  The condition must be confirmed by a histological diagnosis; AND  The treatment must be as monotherapy; or  The treatment must form part of dual combination therapy limited to:   (i) this drug, (ii) dexamethasone; AND  Patient must have progressive disease after at least one prior therapy; AND  Patient must have undergone or be ineligible for a primary stem cell transplant.  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.  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  (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and  (2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and  (3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and  (4) details of the basis of the diagnosis of progressive disease or failure to respond; and  (5) nomination of which disease activity parameters will be used to assess response.  (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.  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 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). | Compliance with Written Authority Required procedures |
| C13804 | P13804 | CN13804 | Lenalidomide | Multiple myeloma  Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease  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  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. | Compliance with Authority Required procedures |
| C13805 | P13805 | CN13805 | Lenalidomide | 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. | Compliance with Authority Required procedures |
| C13810 | P13810 | CN13810 | Lenalidomide | 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  Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities; AND  Patient must be red blood cell transfusion dependent.  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.  Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations  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.  Classification of a patient as red blood cell transfusion dependent requires that  (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.  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 from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and  (b) details (date, unique identifying number/code or provider number) of the full blood examination report; and  (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  (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.  All the reports must be documented in the patient's medical records.  If the application is submitted through HPOS upload or mail, it must include  (a) a completed authority prescription form; and  (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). | Compliance with Authority Required procedures |
| C13811 | P13811 | CN13811 | Lenalidomide | Multiple myeloma  Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)  Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND  The treatment must form part of triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND  The treatment must not exceed a total of 4 cycles under this restriction. | Compliance with Authority Required procedures |
| C13812 | P13812 | CN13812 | Lenalidomide | Multiple myeloma  Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation  The condition must be newly diagnosed; AND  The condition must be confirmed by a histological diagnosis; AND  Patient must be ineligible for a primary stem cell transplantation; AND  The treatment must form part of dual combination therapy limited to:   (i) this drug, (ii) dexamethasone.  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  (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.  (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.  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/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.  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 |
| C13813 | P13813 | CN13813 | Lenalidomide | Multiple myeloma  Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)  Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND  The treatment must form part of triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; AND  The treatment must not exceed a total of 2 cycles under this restriction. | Compliance with Authority Required procedures |
| C13819 | P13819 | CN13819 | Romosozumab | Severe established osteoporosis  Initial treatment  Patient must be at very high risk of fracture; AND  Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND  Patient must have had 2 or more fractures due to minimal trauma; AND  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  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a lifetime maximum of 12 months therapy; AND  Patient must not have received treatment with PBS-subsidised teriparatide; or  Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy; AND  Must be treated by a consultant physician.  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.  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.  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.  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. | Compliance with Authority Required procedures |
| C13820 | P13820 | CN13820 | Romosozumab | Severe established osteoporosis  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must not exceed a lifetime maximum of 12 months therapy; AND  Must be treated by a medical practitioner identifying as either:   (i) a consultant physician, (ii) a general practitioner. | Compliance with Authority Required procedures |
| C13821 | P13821 | CN13821 | Nirmatrelvir and ritonavir | SARS-CoV-2 infection  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  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  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.  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; OR  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.  a. Chemotherapy or whole body radiotherapy,  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,  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),  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  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.  Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records  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.  Access to this drug through this restriction is permitted irrespective of vaccination status.  Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.  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.  This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | Compliance with Authority Required procedures - Streamlined Authority Code 13821 |
| C13839 | P13839 | CN13839 | Nivolumab | Unresectable Stage III or Stage IV malignant melanoma  Maintenance treatment  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  The treatment must be as monotherapy for this condition; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this PBS indication.  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.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 13839 |
| C13845 | P13845 | CN13845 | Eculizumab | Paroxysmal nocturnal haemoglobinuria (PNH)  First Continuing Treatment  Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment 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, 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) | Compliance with Authority Required procedures |
| C13852 | P13852 | CN13852 | Nivolumab | Unresectable Stage III or Stage IV malignant melanoma  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for combination induction therapy  Patient must have received non-PBS-subsidised treatment with nivolumab in combination with ipilimumab for this PBS indication prior to 1 March 2023; AND  Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to commencing non-PBS-subsidised treatment; AND  The condition must not be ocular or uveal melanoma; AND  The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.  Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.  Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. | Compliance with Authority Required procedures - Streamlined Authority Code 13852 |
| C13857 | P13857 | CN13857 | Eculizumab | Paroxysmal nocturnal haemoglobinuria (PNH)  Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)  Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022; AND  Patient must have received insufficient quantity to complete the induction treatment phase; 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 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  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  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  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 to complete the induction treatment phase, 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) | Compliance with Authority Required procedures |
| C13863 | P13863 | CN13863 | Nivolumab | Unresectable Stage III or Stage IV malignant melanoma  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for maintenance treatment  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  The treatment must be as monotherapy for this condition; AND  Patient must not have developed disease progression while receiving treatment with this drug for this PBS indication.  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.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 13863 |
| C13864 | P13864 | CN13864 | Mepolizumab | 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.  Optimised nasal polyp therapy includes  (a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated  (b) if required, nasal irrigation with saline  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.  The authority application must be made in writing and must include  (a) a completed authority prescription form,  (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),  (c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,  (d) details (date and treatment) of nasal polyp surgery; or  (e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,  (f) the eosinophil count and date,  (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. | Compliance with Written Authority Required procedures |
| C13865 | P13865 | CN13865 | Mepolizumab | Chronic rhinosinusitis with nasal polyps (CRSwNP)  Continuing treatment  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 PBS-subsidised treatment with this drug for this condition; AND  Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of:   (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 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. | Compliance with Authority Required procedures |
| C13866 | P13866 | CN13866 | Ruxolitinib | 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).  Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.  Details of prior steroid use should be documented in the patient's medical records.  Response is defined as attaining a complete or partial response as defined by the *National Institutes of Health* (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.  (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.  (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.  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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13866 |
| C13867 | P13867 | CN13867 | Ruxolitinib | Moderate to severe chronic graft versus host disease (cGVHD)  Continuing treatment  Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND  Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a:   (i) partial response, (ii) complete response; 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.  Response is defined as attaining a complete or partial response as defined by the *National Institutes of Health* (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.  (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.  (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.  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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13867 |
| C13868 | P13868 | CN13868 | Sapropterin | Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)  Initial treatment - responsiveness testing  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:   First continuing treatment, Indication: Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU); AND  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  Must be treated by a metabolic physician; AND  Patient must be undergoing treatment with this drug for the first time; AND  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  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. | Compliance with Authority Required procedures |
| C13876 | P13876 | CN13876 | Ruxolitinib | 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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13876 |
| C13877 | P13877 | CN13877 | Ruxolitinib | 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  (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 intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.  Details of prior steroid use should be documented in the patient's medical records.  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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13877 |
| C13880 | P13880 | CN13880 | Sapropterin | Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)  First continuing treatment  Must be treated by a metabolic physician; or  Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND  Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition; AND  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.  Blood phenylalanine levels must be based on measurements taken during stable periods of the condition.  Dietary phenylalanine intake must be maintained at a constant level. | Compliance with Authority Required procedures |
| C13885 | P13885 | CN13885 | Sapropterin | Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)  Initial treatment - responsiveness testing  Must be treated by a metabolic physician; AND  Patient must be untreated with this drug; or  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  Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; or  Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age; AND  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  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.  Dietary phenylalanine intake must be maintained at a constant level.  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. | Compliance with Authority Required procedures |
| C13886 | P13886 | CN13886 | Calcitonin salmon | Hypercalcaemia  The treatment must be initiated in a hospital; AND  The treatment must be for a patient who cannot tolerate bisphosphonates due to kidney disease. | Compliance with Authority Required procedures |
| C13887 | P13887 | CN13887 | Methyldopa | Hypertension  Patient must be pregnant. | Compliance with Authority Required procedures |
| C13890 | P13890 | CN13890 | Mepolizumab | Chronic rhinosinusitis with nasal polyps (CRSwNP)  Initial treatment  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 a diagnosis of CRSwNP confirmed by at least one of:   (i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; or  Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types; AND  Patient must have undergone surgery for the removal of nasal polyps; or  Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery; AND  Patient must have, 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); AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; or  Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition; AND  The treatment must not be 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; AND  Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented; AND  Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months;  Patient must be at least 18 years of age.  Optimised nasal polyp therapy includes  (a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated  (b) if required, nasal irrigation with saline  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.  The authority application must be made in writing and must include  (a) a completed authority prescription form,  (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),  (c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,  (d) details (date and treatment) of nasal polyp surgery; or  (e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,  (f) the eosinophil count and date,  (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. | Compliance with Written Authority Required procedures |
| C13891 | P13891 | CN13891 | Ruxolitinib | 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  (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 intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.  Details of prior steroid use should be documented in the patient's medical records.  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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13891 |
| C13892 | P13892 | CN13892 | Ruxolitinib | 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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13892 |
| C13900 | P13900 | CN13900 | Nivolumab | Adjuvant treatment of stage II or III oesophageal cancer or gastro-oesophageal junction cancer  The condition must have histological evidence confirming a diagnosis of a least one of:   (i) adenocarcinoma, (ii) squamous cell cancer; document this evidence in the patient's medical records; AND  The condition must have been treated with neoadjuvant platinum-based chemoradiotherapy; AND  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  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:   (i) at least ypT1, (ii) at least ypN1; document this evidence in the patient's medical records; AND  Patient must have/have had, 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 therapy for this condition; AND  Patient must be undergoing treatment with a dosing regimen as set out in the drug's approved Australian Product Information; AND  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. | Compliance with Authority Required procedures |
| 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 *National Institutes of Health* (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).  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).  Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.  Details of prior steroid use should be documented in the patient's medical records.  A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment.  Response is defined as attaining a complete or partial response as defined by the *National Institutes of Health* (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.  (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.  (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.  The assessment of response must be documented in the patient's medical records.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13906 |
| C13907 | P13907 | CN13907 | Ruxolitinib | Grade II to IV acute graft versus host disease (aGVHD)  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  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.  The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).  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  (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 intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.  Details of prior steroid use should be documented in the patient's medical records.  A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.  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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13907 |
| C13911 | P13911 | CN13911 | Ruxolitinib | Grade II to IV acute graft versus host disease (aGVHD)  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  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.  The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).  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  (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 intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.  Details of prior steroid use should be documented in the patient's medical records.  A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.  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.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 13911 |
| C13912 | P13912 | CN13912 | Sapropterin | Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)  Subsequent continuing  Must be treated by a metabolic physician; or  Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND  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. | Compliance with Authority Required procedures |
| 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  Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; or  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;  Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND  Patient must require continuous coverage over 8 hours; AND  The treatment must not exceed a maximum daily dose of 80 mg with this drug.  A retrospective diagnosis of ADHD for the purposes of administering this restriction is  (i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and  (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. | Compliance with Authority Required procedures |
| C13923 | P13923 | CN13923 | Asciminib | Chronic Myeloid Leukaemia (CML)  Continuing treatment for patients without T315I mutation  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND  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  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%.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13923 |
| C13925 | P13925 | CN13925 | Asciminib | Chronic Myeloid Leukaemia (CML)  Initial PBS-subsidised treatment for patients with T315I mutation  The condition must not be in the blast phase; AND  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  1. Lack of response defined as either  (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.  Accelerated phase is defined by the presence of 1 or more of the following  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).  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  (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  (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  (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and  (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.  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).  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  Up to a maximum of 18 months of treatment may be authorised under this initial restriction. | Compliance with Written Authority Required procedures |
| C13927 | P13927 | CN13927 | Ustekinumab | 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; 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.  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 biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website. | Compliance with Authority Required procedures |
| C13929 | P13929 | CN13929 | Vosoritide | Achondroplasia  Grandfather treatment (transition from non-PBS subsidised treatment)  Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing; AND  Patient must have received non-PBS subsidised vosoritide treatment for this condition prior to 1 May 2023; AND  Patient must not have evidence of growth plate closure demonstrated by at least one of the following:   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  Must be treated by a medical specialist, experienced in the management of achondroplasia. or  Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.  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.  Appropriate genetic testing constitutes testing for FGFR3 gene mutation.  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.  Additional radiographic evidence is not required until patient has begun puberty.  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. | Compliance with Authority Required procedures |
| C13930 | P13930 | CN13930 | Upadacitinib | Moderate to severe ulcerative colitis  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  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 non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND  Patient must be receiving treatment with this drug for this condition at the time of application; AND  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  Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND  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  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  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  Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND  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  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  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;  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. | Compliance with Written Authority Required procedures |
| C13932 | P13932 | CN13932 | Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | Cystic fibrosis  Initial 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 at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene; AND  The treatment must be given concomitantly with standard therapy for this condition; AND  Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug;  Patient must be aged between 6 and 11 years inclusive.  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 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. | Compliance with Authority Required procedures |
| C13936 | P13936 | CN13936 | Memantine | Moderately severe Alzheimer disease  Initial  Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND  The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND  The treatment must be the sole PBS-subsidised therapy for this condition.  A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.  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.  Patients who qualify under this criterion are from 1 or more of the following groups  (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.  Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | Compliance with Authority Required procedures |
| C13938 | P13938 | CN13938 | Donepezil  Galantamine  Rivastigmine | Mild to moderately severe Alzheimer disease  Continuing  Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND  Patient must demonstrate a clinically meaningful response to the initial treatment; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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.  Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.  Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.  Clinically meaningful response to treatment is demonstrated in the following areas  Patient's quality of life including but not limited to level of independence and happiness;  Patient's cognitive function including but not limited to memory, recognition and interest in environment;  Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour. | Compliance with Authority Required procedures - Streamlined Authority Code 13938 |
| C13940 | P13940 | CN13940 | Donepezil  Galantamine  Rivastigmine | Mild to moderately severe Alzheimer disease  Initial  Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND  The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND  The treatment must be the sole PBS-subsidised therapy for this condition.  A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.  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.  Patients who qualify under this criterion are from 1 or more of the following groups  (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.  Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | Compliance with Authority Required procedures |
| C13941 | P13941 | CN13941 | Donepezil  Galantamine  Rivastigmine | Mild to moderately severe Alzheimer disease  Initial  Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND  The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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.  Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | Compliance with Authority Required procedures |
| C13944 | P13944 | CN13944 | Daratumumab | Newly diagnosed systemic light chain amyloidosis  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January 2023; AND  The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND  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  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  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  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  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.  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  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  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).  Determine an appropriate number of repeat prescriptions for this authority application in line with either  (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  (ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions. | Compliance with Authority Required procedures |
| C13945 | P13945 | CN13945 | Abiraterone | Castration resistant metastatic carcinoma of the prostate  The treatment must be used in combination with a corticosteroid; AND  The treatment must not be used in combination with chemotherapy; AND  Patient must have a WHO performance status of 2 or less; AND  The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of:   (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits; 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. | Compliance with Authority Required procedures |
| C13946 | P13946 | CN13946 | Ozanimod | Moderate to severe ulcerative colitis  Continuing treatment - balance of supply  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 insufficient therapy with this drug for this condition under the continuing 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 restriction. | Compliance with Authority Required procedures |
| C13948 | P13948 | CN13948 | Pembrolizumab | 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 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; 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. | Compliance with Authority Required procedures - Streamlined Authority Code 13948 |
| C13949 | P13949 | CN13949 | Pembrolizumab | Stage IV clear cell variant renal cell carcinoma (RCC)  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  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; 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; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13949 |
| C13950 | P13950 | CN13950 | Asciminib | Chronic Myeloid Leukaemia (CML)  Initial PBS-subsidised treatment for patients without T315I mutation  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The condition must not be in the blast phase; AND  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  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 two tyrosine kinase inhibitors. or  Patient must have experienced intolerance, not failure to respond, to at least two tyrosine kinase inhibitors. or  Patient must have failed an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor.  Failure of an adequate trial of a tyrosine kinase inhibitor is defined as  1. Lack of response defined as either  (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.  Accelerated phase is defined by the presence of 1 or more of the following  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). | Compliance with Authority Required procedures |
| C13952 | P13952 | CN13952 | Ustekinumab | Moderate to severe ulcerative colitis  Continuing treatment - balance of supply  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 insufficient therapy with this drug for this condition under the continuing 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 restriction. | Compliance with Authority Required procedures |
| C13955 | P13955 | CN13955 | Ustekinumab | 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.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  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.  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 maximum of 16 weeks of treatment with this drug will be approved under this criterion.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website. | Compliance with Authority Required procedures |
| C13958 | P13958 | CN13958 | Upadacitinib | Moderate to severe ulcerative colitis  Continuing treatment - balance of supply  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  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:   (i) the quantity per dispensing, (ii) repeat prescriptions; AND  The treatment must provide no more than the balance of 24 weeks treatment. | Compliance with Authority Required procedures |
| C13959 | P13959 | CN13959 | Upadacitinib | Moderate to severe ulcerative colitis  Dose modification  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 existing PBS-subsidised treatment with this therapy. | Compliance with Authority Required procedures |
| C13962 | P13962 | CN13962 | Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | Cystic fibrosis  Initial 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 at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene; AND  The treatment must be given concomitantly with standard therapy for this condition; AND  Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug;  Patient must be at least 6 years of age.  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 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. | Compliance with Authority Required procedures |
| C13966 | P13966 | CN13966 | Memantine | Moderately severe Alzheimer disease  Continuing  Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND  Patient must demonstrate a clinically meaningful response to the initial treatment; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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.  Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.  Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.  Clinically meaningful response to treatment is demonstrated in the following areas  Patient's quality of life including but not limited to level of independence and happiness;  Patient's cognitive function including but not limited to memory, recognition and interest in environment;  Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour. | Compliance with Authority Required procedures - Streamlined Authority Code 13966 |
| C13967 | P13967 | CN13967 | Naltrexone | Alcohol dependence  The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption. | Compliance with Authority Required procedures - Streamlined Authority Code 13967 |
| C13972 | P13972 | CN13972 | Lenvatinib | Stage IV clear cell variant renal cell carcinoma (RCC)  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  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. or  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.  In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record. | Compliance with Authority Required procedures - Streamlined Authority Code 13972 |
| C13975 | P13975 | CN13975 | Ustekinumab | 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  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  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  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 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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].  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.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  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.  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.  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.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion.  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. | Compliance with Authority Required procedures |
| C13976 | P13976 | CN13976 | Ustekinumab | 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; 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 biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website. | Compliance with Authority Required procedures |
| C13977 | P13977 | CN13977 | Vosoritide | Achondroplasia  Initial treatment  Patient must have a diagnosis of achondroplasia, confirmed by appropriate genetic testing; AND  Patient must not have evidence of growth plate closure demonstrated by at least one of the following:   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  Must be treated by a medical specialist, experienced in the management of achondroplasia. or  Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.  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.  Appropriate genetic testing constitutes testing for FGFR3 gene mutation.  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.  Additional radiographic evidence is not required until patient has begun puberty.  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. | Compliance with Authority Required procedures |
| C13980 | P13980 | CN13980 | Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | 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 given concomitantly with standard therapy for this condition;  Patient must be at least 6 years of age.  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. | Compliance with Authority Required procedures |
| C13986 | P13986 | CN13986 | Pembrolizumab | Stage IV clear cell variant renal cell carcinoma (RCC)  Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements  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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 13986 |
| C13988 | P13988 | CN13988 | Ustekinumab | 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  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  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  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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].  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.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  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.  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.  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.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion.  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. | Compliance with Authority Required procedures |
| C13990 | P13990 | CN13990 | Upadacitinib | 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);  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.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  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 maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C13991 | P13991 | CN13991 | Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | 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 given concomitantly with standard therapy for this condition;  Patient must be aged between 6 and 11 years inclusive.  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. | Compliance with Authority Required procedures |
| C13992 | P13992 | CN13992 | Abiraterone and methylprednisolone | Castration resistant metastatic carcinoma of the prostate  The treatment must not be used in combination with chemotherapy; AND  Patient must have a WHO performance status of 2 or less; AND  The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of:   (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits; 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. | Compliance with Authority Required procedures |
| C13993 | P13993 | CN13993 | Ozanimod | Moderate to severe ulcerative colitis  Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements  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 non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND  Patient must be receiving treatment with this drug for this condition at the time of application; AND  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  Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND  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  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  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  Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND  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  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  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  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. | Compliance with Written Authority Required procedures |
| C13995 | P13995 | CN13995 | Ozanimod | 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  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  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  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);  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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].  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.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 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.  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.  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.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C13998 | P13998 | CN13998 | Vosoritide | Achondroplasia  Continuing treatment  Patient must have received PBS subsidised vosoritide treatment for this condition; AND  Patient must not have evidence of growth plate closure demonstrated by at least one of the following:   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  Must be treated by a medical specialist, experienced in the management of achondroplasia. or  Must be treated by a paediatrician in consultation with a medical specialist experienced in the management of achondroplasia.  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.  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.  Additional radiographic evidence is not required until patient has begun puberty.  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. | Compliance with Authority Required procedures |
| C13999 | P13999 | CN13999 | Upadacitinib | Moderate to severe ulcerative colitis  Initial treatment - Initial 1 (new patient - untreated with biological medicine)  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  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  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  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);  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) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].  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.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  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.  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.  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.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C14000 | P14000 | CN14000 | Memantine | Moderately severe Alzheimer disease  Initial  Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14; AND  The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND  The treatment must be the sole PBS-subsidised therapy for this condition.  The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.  Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | Compliance with Authority Required procedures |
| C14001 | P14001 | CN14001 | Nivolumab | Stage IV clear cell variant renal cell carcinoma (RCC)  Induction treatment  The condition must not have previously been treated; AND  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  Patient must have a WHO performance status of 2 or less; AND  The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.  Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 14001 |
| C14002 | P14002 | CN14002 | Ozanimod | Moderate to severe ulcerative colitis  Continuing treatment  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 this drug for this condition; AND  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;  Patient must be at least 18 years of age.  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.  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.  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 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. | Compliance with Authority Required procedures |
| C14003 | P14003 | CN14003 | Ozanimod | 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.  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 biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C14004 | P14004 | CN14004 | Ozanimod | 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);  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.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 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 maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C14005 | P14005 | CN14005 | Ozanimod | Moderate to severe ulcerative colitis  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  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 insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  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  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  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C14007 | P14007 | CN14007 | Lenvatinib | Stage IV clear cell variant renal cell carcinoma (RCC)  Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements  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  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:   (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, (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14007 |
| C14008 | P14008 | CN14008 | Asciminib | Chronic Myeloid Leukaemia (CML)  Continuing Treatment for patients with T315I mutation  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 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  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%.  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.  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  (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).  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 | Compliance with Authority Required procedures |
| C14009 | P14009 | CN14009 | Ustekinumab | Moderate to severe ulcerative colitis  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  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 non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND  Patient must be receiving treatment with this drug for this condition at the time of application; AND  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  Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND  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  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  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  Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND  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  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  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  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  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. | Compliance with Written Authority Required procedures |
| C14010 | P14010 | CN14010 | Ustekinumab | 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 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.  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.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  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.  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 maximum of 16 weeks of treatment with this drug will be approved under this criterion.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website. | Compliance with Authority Required procedures |
| C14011 | P14011 | CN14011 | Upadacitinib | Moderate to severe ulcerative colitis  Continuing treatment  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 this drug for this condition; AND  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;  Patient must be at least 18 years of age.  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.  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.  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 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. | Compliance with Authority Required procedures |
| C14014 | P14014 | CN14014 | Upadacitinib | 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 if relevant; 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 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 biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C14015 | P14015 | CN14015 | Daratumumab | Newly diagnosed systemic light chain amyloidosis  Initial treatment from week 0 to week 24  The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND  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  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  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  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.  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  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  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 Authority Required procedures |
| C14017 | P14017 | CN14017 | Ozanimod | Moderate to severe ulcerative colitis  Dose escalation occurring at initial treatment or re-initiation of treatment  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)]. | Compliance with Authority Required procedures - Streamlined Authority Code 14017 |
| C14018 | P14018 | CN14018 | Ustekinumab | Moderate to severe ulcerative colitis  Continuing treatment  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 this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  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  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be at least 18 years of age.  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.  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.  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 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. | Compliance with Authority Required procedures |
| C14021 | P14021 | CN14021 | Selinexor | Relapsed and/or refractory multiple myeloma  Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week  The condition must be confirmed by a histological diagnosis; AND  Patient must be undergoing triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; or  Patient must be undergoing dual combination therapy limited to:   (i) this drug, (ii) dexamethasone; AND  Patient must have progressive disease after at least one prior therapy; AND  Patient must not have previously received 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.  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.  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  (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; 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 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.  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 | Compliance with Authority Required procedures |
| C14022 | P14022 | CN14022 | Selinexor | Relapsed and/or refractory multiple myeloma  Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg, 60 mg or 40 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 progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug; AND  Patient must not have developed disease progression 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. | Compliance with Authority Required procedures |
| C14023 | P14023 | CN14023 | Selinexor | Relapsed and/or refractory multiple myeloma  Continuing treatment - Dose requirement of 100 mg per week  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must be undergoing triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; or  Patient must be undergoing dual combination therapy limited to:   (i) this drug, (ii) dexamethasone; AND  Patient must not have developed disease progression 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. | Compliance with Authority Required procedures |
| C14024 | P14024 | CN14024 | Selinexor | Relapsed and/or refractory multiple myeloma  Initial treatment - Dose requirement of 100 mg per week  The condition must be confirmed by a histological diagnosis; AND  Patient must be undergoing triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; or  Patient must be undergoing dual combination therapy limited to:   (i) this drug, (ii) dexamethasone; AND  Patient must have progressive disease after at least one prior therapy; AND  Patient must not have previously received 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.  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 | Compliance with Authority Required procedures |
| C14026 | P14026 | CN14026 | Ciclosporin | Chronic severe dry eye disease with keratitis  Initial treatment for up to the first 180 days of treatment  Patient must have a corneal fluorescein staining (CFS) grade of 4 at treatment initiation, using at least one of:   (i) the Oxford scale, (ii) the modified Oxford scale, (iii) an equivalent scale to the Oxford scale as determined by the prescriber; AND  Patient must have an ocular surface disease index (OSDI) score of at least 23 at treatment initiation; AND  The condition must be inadequately controlled by monotherapy with a preservative free artificial tears substitute; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must be undergoing simultaneous treatment with a preservative free artificial tears substitute; AND  Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; or  Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines; AND  Patient must not be undergoing treatment with this drug under this treatment phase beyond day 180 of treatment;  Patient must be at least 18 years of age.  Prescribing instruction  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). | Compliance with Authority Required procedures |
| C14027 | P14027 | CN14027 | Pembrolizumab | Advanced, metastatic or recurrent endometrial carcinoma  Initial treatment  Patient must have received prior treatment with platinum-based chemotherapy; AND  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  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  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; 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14027 |
| C14028 | P14028 | CN14028 | Pembrolizumab | Advanced, metastatic or recurrent endometrial carcinoma  Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements  Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND  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 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14028 |
| C14031 | P14031 | CN14031 | Selinexor | Relapsed and/or refractory multiple myeloma  Continuing treatment - Dose requirement of 160 mg per week  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must be undergoing dual combination therapy limited to:   (i) this drug, (ii) dexamethasone; AND  Patient must not have developed disease progression 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. | Compliance with Authority Required procedures |
| C14032 | P14032 | CN14032 | Ciclosporin | Chronic severe dry eye disease with keratitis  Continuing treatment  Patient must have received PBS-subsidised treatment with this drug for this condition; AND  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  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  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. or  Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines.  Prescribing instructions  State in the first continuing treatment authority application for this drug  (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). | Compliance with Authority Required procedures |
| 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 progressed (see definition of progressive disease below) after at least one prior therapy, (d) the patient had never been treated with this drug; AND  Patient must not have developed disease progression 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. | Compliance with Authority Required procedures |
| C14039 | P14039 | CN14039 | Selinexor | Relapsed and/or refractory multiple myeloma  Initial treatment - Dose requirement of 160 mg per week  The condition must be confirmed by a histological diagnosis; AND  Patient must be undergoing dual combination therapy limited to:   (i) this drug, (ii) dexamethasone; AND  Patient must have progressive disease after at least one prior therapy; AND  Patient must not have previously received 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.  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 | Compliance with Authority Required procedures |
| C14040 | P14040 | CN14040 | Nicotine | Nicotine dependence  The treatment must be as an aid to achieving abstinence from smoking; AND  The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation; AND  Patient must have indicated they are ready to cease smoking; AND  Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period; AND  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.  Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated. |  |
| C14041 | P14041 | CN14041 | Lenvatinib | Advanced, metastatic or recurrent endometrial carcinoma  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 PBS-subsidised treatment with this drug for this condition; 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. or  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14041 |
| C14042 | P14042 | CN14042 | Lenvatinib | Advanced, metastatic or recurrent endometrial carcinoma  Initial treatment  Patient must have received prior treatment with platinum-based chemotherapy; AND  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  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  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 14042 |
| C14043 | P14043 | CN14043 | Lenvatinib | Advanced, metastatic or recurrent endometrial carcinoma  Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements  Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND  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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14043 |
| C14044 | P14044 | CN14044 | Pembrolizumab | Advanced, metastatic or recurrent endometrial carcinoma  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 PBS-subsidised treatment with this drug for this condition; 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; 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; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14044 |
| C14045 | P14045 | CN14045 | Selinexor | Relapsed and/or refractory multiple myeloma  Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must be undergoing triple combination therapy limited to:   (i) this drug, (ii) bortezomib, (iii) dexamethasone; or  Patient must be undergoing dual combination therapy limited to:   (i) this drug, (ii) dexamethasone; AND  Patient must not have developed disease progression 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. | Compliance with Authority Required procedures |
| C14047 | P14047 | CN14047 | Cannabidiol | Seizures of the Lennox-Gastaut syndrome  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  Patient must have (as an initiating patient)/have had (as a continuing patient) more than one type of generalised seizures; AND  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  The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs; AND  Must be treated by a neurologist if treatment is being initiated. or  Must be treated by a neurologist if treatment is being continued or re-initiated. or  Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued. or  Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.  Tonic seizures must have been recorded on video-EEG or have been clearly observed and reported by a witness.  Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C14054 | P14054 | CN14054 | Avatrombopag | Severe thrombocytopenia  Second or Subsequent Continuing treatment  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  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  Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug; AND  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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. | Compliance with Authority Required procedures |
| C14061 | P14061 | CN14061 | Adalimumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less 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 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; AND  Patient must not receive more than 16 weeks of treatment 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.  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.  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.  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 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.  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. | Compliance with Authority Required procedures |
| C14063 | P14063 | CN14063 | Adalimumab | 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).  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.  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.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic; and  (b) the date of the last continuing prescription.  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.  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. | Compliance with Authority Required procedures |
| C14064 | P14064 | CN14064 | Adalimumab | 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 methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.  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.  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.  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.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  (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  (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 prior treatment must be documented in the patient's medical records.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) details of prior treatment including dose and duration of treatment.  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.  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.  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. | Compliance with Authority Required procedures |
| C14068 | P14068 | CN14068 | Etanercept | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less 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 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; AND  Patient must not receive more than 16 weeks of treatment 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.  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.  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.  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 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.  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. | Compliance with Authority Required procedures |
| C14070 | P14070 | CN14070 | Etanercept | 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 methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.  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.  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.  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.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  (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  (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 prior treatment must be documented in the patient's medical records.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) details of prior treatment including dose and duration of treatment.  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.  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.  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. | Compliance with Authority Required procedures |
| C14071 | P14071 | CN14071 | Etanercept | 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).  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.  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.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) the date of the last continuing prescription.  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.  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. | Compliance with Authority Required procedures |
| C14074 | P14074 | CN14074 | Buprenorphine with naloxone | Opioid dependence  The treatment must be within a framework of medical, social and psychological treatment.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14074 |
| C14075 | P14075 | CN14075 | Buprenorphine | Opioid dependence  Must be treated by a health care professional; AND  The treatment must be within a framework of medical, social and psychological treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 14075 |
| C14080 | P14080 | CN14080 | Tocilizumab | Systemic juvenile idiopathic arthritis  Initial treatment - Initial 1 (new patient weighing at least 30 kg)  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.  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  (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).  The assessment of response to prior treatment must be documented in the patient's medical records.  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  (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).  The assessment of response to prior treatment must be documented in the patient's medical records.  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.  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.  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.  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.  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.  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.  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 information must be provided by the prescriber at the time of application and documented in the patient's medical records  (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. | Compliance with Authority Required procedures |
| C14082 | P14082 | CN14082 | Tocilizumab | 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.  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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14082 |
| C14083 | P14083 | CN14083 | Tocilizumab | 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).  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.  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.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) the date of the last continuing prescription.  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.  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. | Compliance with Authority Required procedures |
| C14084 | P14084 | CN14084 | Tocilizumab | Systemic juvenile idiopathic arthritis  Continuing treatment in a patient weighing less than 30 kg  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  (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.  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.  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.  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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14084 |
| C14085 | P14085 | CN14085 | Tocilizumab | Systemic juvenile idiopathic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND  Patient must have polyarticular course disease and the condition must have at least one of:   (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  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  Patient must not receive more than 16 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;  Patient must be under 18 years of age.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active systemic juvenile idiopathic arthritis.  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.  The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.  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.  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.  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 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. | Compliance with Authority Required procedures |
| C14088 | P14088 | CN14088 | Tocilizumab | Systemic juvenile idiopathic arthritis  Continuing treatment in a patient weighing at least 30 kg  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  (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.  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.  The following reports must be documented in the patient's medical records where appropriate  (a) baseline and current pathology reports detailing C-reactive protein (CRP) levels; and  (b) baseline and current pathology reports detailing platelet count.  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.  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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14088 |
| C14091 | P14091 | CN14091 | Tocilizumab | Systemic juvenile idiopathic arthritis  Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)  Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND  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  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.  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.  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 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 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.  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 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. | Compliance with Authority Required procedures |
| C14093 | P14093 | CN14093 | Tocilizumab | 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  (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.  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.  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.  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.  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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14093 |
| C14094 | P14094 | CN14094 | Tocilizumab | Systemic juvenile idiopathic arthritis  Initial treatment - Initial 1 (new patient weighing less than 30 kg)  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.  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  (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).  The assessment of response to prior treatment must be documented in the patient's medical records.  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  (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).  The assessment of response to prior treatment must be documented in the patient's medical records.  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.  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.  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.  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.  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.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (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.  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. | Compliance with Authority Required procedures |
| C14096 | P14096 | CN14096 | Choriogonadotropin alfa | Infertility indications other than that of Assisted Reproductive Technology  Patient must not be undergoing treatment with medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule; AND  Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing; AND  Must be treated by an obstetrician/gynaecologist. or  Must be treated by a specialist in reproductive endocrinology/infertility. or  Must be treated by a urogynaecologist. or  Must be treated by an endocrinologist. or  Must be treated by a urologist.  The PBS prescription, whether it is to initiate or continue treatment, must be made out under the specialist's prescriber number. |  |
| C14097 | P14097 | CN14097 | Finerenone | Chronic kidney disease with Type 2 diabetes  Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of:   (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND  Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug; AND  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  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  Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND  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  The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant; AND  Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic; AND  Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist. | Compliance with Authority Required procedures - Streamlined Authority Code 14097 |
| C14098 | P14098 | CN14098 | Romiplostim | Severe thrombocytopenia  Initial treatment - New patient  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND  Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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;  (a) a platelet count of less than or equal to 20,000 million per L; OR  (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.  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.  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.  Authority approval will not be given for doses higher than 10 micrograms/kg/week  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.  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. | Compliance with Written Authority Required procedures |
| C14099 | P14099 | CN14099 | Romiplostim | Severe thrombocytopenia  First Continuing treatment or Re-initiation of interrupted continuing treatment  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  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  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  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  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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.  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.  Authority approval will not be given for doses higher than 10 micrograms/kg/week  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. | Compliance with Authority Required procedures |
| C14101 | P14101 | CN14101 | Avatrombopag | Severe thrombocytopenia  First Continuing treatment or Re-initiation of interrupted continuing treatment  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  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  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  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  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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.  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. | Compliance with Authority Required procedures |
| C14103 | P14103 | CN14103 | Tocilizumab | 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.  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.  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.  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.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  (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  (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 prior treatment must be documented in the patient's medical records.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) details of prior treatment including dose and duration of treatment.  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.  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.  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. | Compliance with Authority Required procedures |
| C14104 | P14104 | CN14104 | Tocilizumab | 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 be under 30kg; 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.  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 in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14104 |
| C14107 | P14107 | CN14107 | Adalimumab | 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.  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.  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 in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14107 |
| C14121 | P14121 | CN14121 | Tocilizumab | Systemic juvenile idiopathic arthritis  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)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND  Patient must have polyarticular course disease and the condition must have at least one of:   (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  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  Patient must not receive more than 16 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;  Patient must be under 18 years of age.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active systemic juvenile idiopathic arthritis.  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.  The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.  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.  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 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. | Compliance with Authority Required procedures |
| C14124 | P14124 | CN14124 | Choriogonadotropin alfa | Assisted Reproductive Technology  Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule; AND  Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing. | Compliance with Authority Required procedures - Streamlined Authority Code 14124 |
| C14126 | P14126 | CN14126 | Eltrombopag | Severe thrombocytopenia  Initial treatment - New patient  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND  Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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;  (a) a platelet count of less than or equal to 20,000 million per L; OR  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C14127 | P14127 | CN14127 | Eltrombopag | 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. | Compliance with Authority Required procedures |
| C14129 | P14129 | CN14129 | Eltrombopag | Severe thrombocytopenia  First Continuing treatment or Re-initiation of interrupted continuing treatment  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  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  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  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  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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.  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. | Compliance with Authority Required procedures |
| C14130 | P14130 | CN14130 | Avatrombopag | Severe thrombocytopenia  Initial treatment - New patient  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy; AND  Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy; AND  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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;  (a) a platelet count of less than or equal to 20,000 million per L; OR  (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.  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.  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.  A maximum of 24 weeks of treatment with this drug will be authorised under this criterion. | Compliance with Written Authority Required procedures |
| C14131 | P14131 | CN14131 | Avatrombopag | 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 have received insufficient therapy with this drug for this condition under the Grandfather treatment restriction; or  Patient must be changing therapy from romiplostim or eltrombopag 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 eltrombopag may change to avatrombopag under this restriction. | Compliance with Authority Required procedures |
| C14132 | P14132 | CN14132 | Avatrombopag | Severe thrombocytopenia  Grandfather treatment  The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP); AND  Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2023; AND  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  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  Patient must have demonstrated a sustained platelet response to the non-PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.  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.  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 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;  (a) a platelet count of less than or equal to 20,000 million per L; OR  (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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14136 | P14136 | CN14136 | Adalimumab | 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.  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.  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 in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14136 |
| C14138 | P14138 | CN14138 | Buprenorphine | Opioid dependence  Must be treated by a health care professional; AND  The treatment must be within a framework of medical, social and psychological treatment; AND  Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14138 |
| C14139 | P14139 | CN14139 | Buprenorphine | Opioid dependence  Must be treated by a health care professional; AND  The treatment must be within a framework of medical, social and psychological treatment; AND  Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition:   (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone. | Compliance with Authority Required procedures - Streamlined Authority Code 14139 |
| C14145 | P14145 | CN14145 | Tocilizumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less 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 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; AND  Patient must not receive more than 16 weeks of treatment 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.  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.  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.  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 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.  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. | Compliance with Authority Required procedures |
| C14147 | P14147 | CN14147 | Tocilizumab | Systemic juvenile idiopathic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have had a break in treatment of 12 months or more from this drug for this condition; AND  Patient must have polyarticular course disease and the condition must have at least one of:   (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  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  Patient must not receive more than 16 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;  Patient must be under 18 years of age.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active systemic juvenile idiopathic arthritis.  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.  The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.  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.  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 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. | Compliance with Authority Required procedures |
| C14148 | P14148 | CN14148 | Tocilizumab | 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.  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  (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).  The assessment of response to prior treatment must be documented in the patient's medical records.  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  (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).  The assessment of response to prior treatment must be documented in the patient's medical records.  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.  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.  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.  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.  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.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (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. | Compliance with Authority Required procedures |
| C14149 | P14149 | CN14149 | Romiplostim | 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. | Compliance with Authority Required procedures |
| C14150 | P14150 | CN14150 | Tocilizumab | 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 be 30kg or over; 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.  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 in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14150 |
| C14153 | P14153 | CN14153 | Tocilizumab | 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.  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.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) the date of the last continuing prescription.  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.  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. | Compliance with Authority Required procedures |
| C14154 | P14154 | CN14154 | Etanercept | 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.  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 in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14154 |
| C14155 | P14155 | CN14155 | Etanercept | 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.  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 in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14155 |
| C14157 | P14157 | CN14157 | Buprenorphine | Opioid dependence  The treatment must be within a framework of medical, social and psychological treatment.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14157 |
| C14162 | P14162 | CN14162 | Tocilizumab | 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 methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.  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.  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.  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.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  (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  (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 prior treatment must be documented in the patient's medical records.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) details of prior treatment including dose and duration of treatment.  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.  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.  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. | Compliance with Authority Required procedures |
| C14164 | P14164 | CN14164 | Tocilizumab | 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.  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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14164 |
| C14166 | P14166 | CN14166 | Tocilizumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less 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 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.  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.  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.  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.  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 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.  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. | Compliance with Authority Required procedures |
| C14175 | P14175 | CN14175 | Tocilizumab | Systemic juvenile idiopathic arthritis  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)  Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND  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  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.  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 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.  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 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. | Compliance with Authority Required procedures |
| C14178 | P14178 | CN14178 | Methadone | Opioid dependence  The treatment must be within a framework of medical, social and psychological treatment.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14178 |
| C14179 | P14179 | CN14179 | Tocilizumab | 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  (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.  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.  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.  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.  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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14179 |
| C14180 | P14180 | CN14180 | Fluticasone propionate | Asthma  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14180 |
| C14182 | P14182 | CN14182 | Tocilizumab | Systemic juvenile idiopathic arthritis  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)  Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months; AND  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  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.  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 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.  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 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. | Compliance with Authority Required procedures |
| C14188 | P14188 | CN14188 | Trabectedin | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14188 |
| C14189 | P14189 | CN14189 | Eptinezumab | Chronic migraine  Initial treatment  Must be treated by a neurologist; AND  Patient must not be undergoing concurrent treatment with the following PBS benefits:   (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  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  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  Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug;  Patient must be at least 18 years of age.  Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.  Patient must have the number of migraine days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14189 |
| C14195 | P14195 | CN14195 | Tocilizumab | Active giant cell arteritis  Initial treatment  Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis; AND  Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause; AND  Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; or  Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; or  Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging; AND  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  Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; or  Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; or  Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis; AND  The treatment must be in combination with a tapering course of corticosteroids; AND  The treatment must not exceed 52 weeks in total including initial and continuing applications;  Patient must be aged 50 years or older.  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.  The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include  (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  (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.  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 Authority Required procedures |
| C14196 | P14196 | CN14196 | Trabectedin | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14196 |
| C14197 | P14197 | CN14197 | Trabectedin | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14197 |
| C14202 | P14202 | CN14202 | Mifepristone and misoprostol | Termination of an intra-uterine pregnancy  The condition must be an intra-uterine pregnancy of up to 63 days of gestation. | Compliance with Authority Required procedures - Streamlined Authority Code 14202 |
| C14217 | P14217 | CN14217 | Upadacitinib | 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  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  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  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  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 non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C14228 | P14228 | CN14228 | Calcium | Hyperphosphataemia  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 associated with chronic renal failure. | Compliance with Authority Required procedures - Streamlined Authority Code 14228 |
| C14229 | P14229 | CN14229 | Mesalazine | Crohn disease  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| C14231 | P14231 | CN14231 | Calcitriol | 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 14231 |
| C14234 | P14234 | CN14234 | Risedronic 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. |  |
| C14235 | P14235 | CN14235 | Risedronic 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  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  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. |  |
| C14236 | P14236 | CN14236 | Calcipotriol with betamethasone | Chronic stable plaque type psoriasis vulgaris  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 inadequately controlled by potent topical corticosteroid monotherapy. |  |
| C14238 | P14238 | CN14238 | Acarbose  Allopurinol  Amlodipine  Amlodipine with atorvastatin  Atenolol  Atorvastatin  Baclofen  Candesartan  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  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  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  Ramipril  Rosuvastatin  Simvastatin  Sirolimus  Sodium bicarbonate  Spironolactone  Sulfasalazine  Sulthiame  Tacrolimus  Telmisartan  Toremifene  Trandolapril  Valproic acid  Valsartan  Verapamil | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| 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  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  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. |  |
| C14244 | P14244 | CN14244 | Trandolapril with verapamil | 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 verapamil. |  |
| C14245 | P14245 | CN14245 | Lercanidipine with enalapril  Perindopril with amlodipine  Ramipril with felodipine | 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 dihydropyridine calcium channel blocker. |  |
| C14246 | P14246 | CN14246 | Perindopril with amlodipine | Stable coronary heart disease  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 therapy for coronary heart disease; AND  The condition must be stabilised by treatment with perindopril and amlodipine at the same doses. |  |
| C14249 | P14249 | CN14249 | Ezetimibe | 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  The treatment must be co-administered with an HMG CoA reductase inhibitor (statin); 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14249 |
| C14251 | P14251 | CN14251 | Bisoprolol  Carvedilol  Metoprolol succinate  Nebivolol | Moderate to severe heart failure  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 stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated. |  |
| C14254 | P14254 | CN14254 | Sacubitril with valsartan | Chronic heart failure  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 symptomatic with NYHA classes II, III or IV; AND  Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND  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:   (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  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  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  The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist. | Compliance with Authority Required procedures - Streamlined Authority Code 14254 |
| C14255 | P14255 | CN14255 | Candesartan with hydrochlorothiazide  Irbesartan with hydrochlorothiazide  Olmesartan with hydrochlorothiazide  Telmisartan with hydrochlorothiazide  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. |  |
| 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.  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  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14269 |
| C14270 | P14270 | CN14270 | Carvedilol | Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| C14272 | P14272 | CN14272 | Amlodipine with valsartan and hydrochlorothiazide  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. |  |
| C14274 | P14274 | CN14274 | Raloxifene | Established post-menopausal 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.  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 14274 |
| C14275 | P14275 | CN14275 | Adapalene with benzoyl peroxide | Severe acne vulgaris  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 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14283 |
| 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14284 |
| C14287 | P14287 | CN14287 | Calcitriol | Hypoparathyroidism  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 14287 |
| C14289 | P14289 | CN14289 | Moxonidine | 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. |  |
| C14291 | P14291 | CN14291 | Alendronic 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.  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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14301 |
| 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;  (iv) diabetes mellitus;  (v) heart failure and/or left ventricular ejection fraction 35% or less. | Compliance with Authority Required procedures - Streamlined Authority Code 14308 |
| 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  Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation. | Compliance with Authority Required procedures - Streamlined Authority Code 14313 |
| 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  (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)  (c) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating the blast percentage.  All reports must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C14324 | P14324 | CN14324 | Pembrolizumab | Recurrent, unresectable or metastatic triple negative breast cancer  The condition must have been (up until this drug therapy) untreated in the unresectable/metastatic disease stage; AND  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  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  The treatment must be in combination with chemotherapy; AND  The condition must have both:   (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  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 - both the following are true:   (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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14324 |
| C14326 | P14326 | CN14326 | Obinutuzumab | Chronic lymphocytic leukaemia (CLL)  Combination use with chlorambucil only  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14326 |
| C14327 | P14327 | CN14327 | Patiromer | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14327 |
| C14332 | P14332 | CN14332 | Azacitidine | 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 count greater than 1.0 x 109/L and platelet count greater than or equal to 100 x 109/L.  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 x 109/L or platelet count less than 100 x 109/L. | Compliance with Authority Required procedures |
| C14337 | P14337 | CN14337 | Zanubrutinib | 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. | Compliance with Authority Required procedures |
| C14338 | P14338 | CN14338 | Azacitidine | 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. | Compliance with Authority Required procedures |
| C14340 | P14340 | CN14340 | Venetoclax | 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). | Compliance with Authority Required procedures |
| C14342 | P14342 | CN14342 | Patiromer | 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. | Compliance with Authority Required procedures |
| C14346 | P14346 | CN14346 | Idelalisib | 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  The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment; AND  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  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  The condition must have relapsed or be refractory to at least one prior therapy; AND  The condition must be CD20 positive; 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. | Compliance with Authority Required procedures |
| C14348 | P14348 | CN14348 | Ezetimibe with atorvastatin | 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14348 |
| C14350 | P14350 | CN14350 | Ezetimibe and rosuvastatin | 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 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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14350 |
| C14359 | P14359 | CN14359 | Infliximab | 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 22 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.  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.  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 following  (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].  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.  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. | Compliance with Written Authority Required procedures |
| C14360 | P14360 | CN14360 | Infliximab | 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 22 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.  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) 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.  (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.  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 following  (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].  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. | Compliance with Written Authority Required procedures |
| C14362 | P14362 | CN14362 | Lenalidomide | Relapsed and/or refractory multiple myeloma  Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone  Patient must be undergoing concurrent treatment with carfilzomib obtained through the PBS; AND  Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing. | Compliance with Authority Required procedures |
| C14363 | P14363 | CN14363 | Carfilzomib | Relapsed and/or refractory multiple myeloma  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14363 |
| C14364 | P14364 | CN14364 | Carfilzomib | 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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14364 |
| 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 |
| C14368 | P14368 | CN14368 | Risdiplam | Spinal muscular atrophy (SMA)  Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood  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;  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);  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 initial PBS-subsidised treatment with this drug for untreated disease; or  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  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; 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  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) 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.  In this authority application, confirm  (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. | Compliance with Authority Required procedures |
| C14370 | P14370 | CN14370 | Nusinersen | Spinal muscular atrophy (SMA)  Changing the prescribed therapy  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  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  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. | Compliance with Written Authority Required procedures |
| C14372 | P14372 | CN14372 | Risdiplam | 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  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.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  Application for authorisation of initial treatment must be in writing and must include  (a) a completed authority prescription form; and  (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following  (ii) sign(s) and symptom(s) that the patient has experienced; and  (iii) patient's age at the onset of sign(s) and symptom(s).  i) specification of SMA type (I, II or IIIa); and  (ii) sign(s) and symptom(s) that the patient has experienced; and  (iii) patient's age at the onset of sign(s) and symptom(s).  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. | Compliance with Authority Required procedures |
| C14374 | P14374 | CN14374 | Bimekizumab | 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 24 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.  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 PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  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 following  (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  (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].  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. | Compliance with Written Authority Required procedures |
| C14375 | P14375 | CN14375 | Bimekizumab | Severe chronic plaque psoriasis  Continuing treatment, Whole body  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  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 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 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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14376 | P14376 | CN14376 | Bimekizumab | 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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14377 | P14377 | CN14377 | Adalimumab | 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;  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) 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.  (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  (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  (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].  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 within this treatment cycle. | Compliance with Written Authority Required procedures |
| C14378 | P14378 | CN14378 | Adalimumab | 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.  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  (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  (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  (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].  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.  The PASI assessment for 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. | Compliance with Written Authority Required procedures |
| C14382 | P14382 | CN14382 | Etanercept | 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.  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 1 month 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 1 month 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 1 month following cessation of each course of treatment.  (c) 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 following  (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].  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 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.  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. | Compliance with Written Authority Required procedures |
| C14384 | P14384 | CN14384 | Deucravacitinib | Severe chronic plaque psoriasis  Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; or  Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; or  Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND  The condition must have caused significant interference with quality of life; AND  Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of:   (i) a biological medicine, (ii) ciclosporin, (iii) apremilast; AND  Must be treated by a medical practitioner who is either:   (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; or  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14384 |
| C14387 | P14387 | CN14387 | Fosnetupitant with palonosetron | Nausea and vomiting  The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy; AND  The treatment must be in combination with dexamethasone, unless contraindicated; AND  Patient must be unable to swallow. or  Patient must be contraindicated to oral anti-emetics. | Compliance with Authority Required procedures |
| C14389 | P14389 | CN14389 | Carfilzomib | Relapsed and/or refractory multiple myeloma  Initial treatment for Cycles 1 to 3  The condition must be confirmed by a histological diagnosis; AND  The treatment must be in combination with lenalidomide and dexamethasone; AND  Patient must have progressive disease after at least one prior therapy; AND  Patient must not have previously received 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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14389 |
| C14390 | P14390 | CN14390 | Somatropin | 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  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. | Compliance with Written Authority Required procedures |
| C14392 | P14392 | CN14392 | Risdiplam | 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;  2 units where (ii) applies;  3 units where (iii) applies;  3 units where (iv) applies. | Compliance with Authority Required procedures |
| C14396 | P14396 | CN14396 | Bimekizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (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 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 PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  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 the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  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 following  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C14398 | P14398 | CN14398 | Adalimumab | 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 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) 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.  (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  (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  (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].  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 within this treatment cycle. | Compliance with Written Authority Required procedures |
| C14399 | P14399 | CN14399 | Adalimumab | 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 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  (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  (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  (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].  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.  The PASI assessment for 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. | Compliance with Written Authority Required procedures |
| C14400 | P14400 | CN14400 | Guselkumab | 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 20 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 PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  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 following  (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].  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. | Compliance with Written Authority Required procedures |
| C14403 | P14403 | CN14403 | Pembrolizumab | Advanced carcinoma of the cervix  Initial treatment  The condition must be at least one of (i) persistent carcinoma, (ii) recurrent carcinoma, (iii) metastatic carcinoma of the cervix; AND  The condition must be unsuitable for curative treatment with either of (i) surgical resection, (ii) radiation; AND  Patient must have WHO performance status no higher than 1; AND  Patient must not have received prior treatment for this PBS indication; AND  Patient must be undergoing concomitant treatment with chemotherapy, containing a minimum of:   (i) a platinum-based chemotherapy agent, plus (ii) paclitaxel; 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14403 |
| C14404 | P14404 | CN14404 | Pembrolizumab | Advanced carcinoma of the cervix  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND  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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14404 |
| C14405 | P14405 | CN14405 | Pembrolizumab | Advanced carcinoma of the cervix  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  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  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:   (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  The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND  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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14405 |
| C14408 | P14408 | CN14408 | Risdiplam | Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)  Initial PBS-subsidised treatment with this drug in a child  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/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 initial PBS-subsidised treatment with this drug for untreated disease; or  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  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; 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  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  (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. | Compliance with Authority Required procedures |
| C14412 | P14412 | CN14412 | Bimekizumab | 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  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 authority application must be made in writing and must include  (a) a completed authority prescription form; 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 sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and  (c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  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. | Compliance with Written Authority Required procedures |
| C14415 | P14415 | CN14415 | Ustekinumab | 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 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.  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.  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.  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 following  (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].  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.  The PASI assessment for 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. | Compliance with Written Authority Required procedures |
| C14416 | P14416 | CN14416 | Enfortumab vedotin | Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer  The condition must have progressed on/following both:   (i) platinum-based chemotherapy, (ii) programmed cell death 1/ligand 1 (PD-1/PD-L1) inhibitor therapy; or  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  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 the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND  Patient must be undergoing treatment with this drug for the first time. or  Patient must be undergoing continuing treatment with this drug, with each of the following being true:   (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent. | Compliance with Authority Required procedures - Streamlined Authority Code 14416 |
| C14417 | P14417 | CN14417 | Apremilast | Severe chronic plaque psoriasis  Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; or  Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; or  Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND  The condition must have caused significant interference with quality of life; AND  Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of:   (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib; AND  Must be treated by a medical practitioner who is either:   (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; or  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14417 |
| C14420 | P14420 | CN14420 | Risdiplam | Spinal muscular atrophy (SMA)  Continuing/maintenance treatment in an adult where treatment was initiated in adulthood  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 after the patient's 19th birthday; 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 each of:   (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; or  The treatment must be occurring within the first 104 weeks from the first administered dose; 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.  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.  PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.  Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.  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 (HFMSE) 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). | Compliance with Authority Required procedures |
| C14421 | P14421 | CN14421 | Nusinersen | Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)  Changing the prescribed therapy  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  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. | Compliance with Written Authority Required procedures |
| C14425 | P14425 | CN14425 | Bimekizumab | 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 24 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.  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) 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.  (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  (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  (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].  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. | Compliance with Written Authority Required procedures |
| C14427 | P14427 | CN14427 | Etanercept | 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;  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) 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.  (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.  (c) 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 following  (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].  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 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.  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. | Compliance with Written Authority Required procedures |
| C14428 | P14428 | CN14428 | Guselkumab | 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 20 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) 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.  (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  (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  (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].  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. | Compliance with Written Authority Required procedures |
| C14430 | P14430 | CN14430 | Secukinumab | 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 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) 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.  (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  (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  (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].  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. | Compliance with Written Authority Required procedures |
| C14431 | P14431 | CN14431 | Somatropin | Severe growth hormone deficiency  Initial treatment of childhood onset growth hormone deficiency in a patient who has received 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 PBS-subsidised treatment with this drug for this condition as a child;  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. | Compliance with Written Authority Required procedures |
| C14433 | P14433 | CN14433 | Nusinersen | Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)  Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood  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 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 continuation of existing PBS-subsidised treatment with this drug; AND  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. | Compliance with Authority Required procedures |
| C14435 | P14435 | CN14435 | Risdiplam | Spinal muscular atrophy (SMA)  Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with Type 1 SMA  Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this:   (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  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  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  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 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;  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.  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 symptomatic Type 1 SMA.  Definition  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.  0. Absence of developmental states (1 to 9) listed below  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  (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  (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  (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.  7. Standing alone  (a) Child stands in upright position on both feet (not on the toes) with the back straight;  (b) The leg supports 100% of the child's weight;  (c) There is no contact with a person or object;  (d) Child stands alone for at least 10 seconds.  8. Walking with assistance  (a) Child is in an upright position with the back straight;  (b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;  (c) One leg moves forward while the other supports part of the body weight;  (d) Child takes at least 5 steps in this manner.  9. Walking alone  (a) Child takes at least 5 steps independently in upright position with the back straight;  (b) One leg moves forward while the other supports most of the body weight;  (c) There is no contact with a person or object.  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).  Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.  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. | Compliance with Authority Required procedures |
| C14437 | P14437 | CN14437 | Bimekizumab | 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 the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  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 following  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C14440 | P14440 | CN14440 | Risankizumab | 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 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.  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  (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  (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].  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.  The PASI assessment for 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.  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. | Compliance with Written Authority Required procedures |
| C14442 | P14442 | CN14442 | Ustekinumab | 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.  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) 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.  (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  (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  (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].  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.  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. | Compliance with Written Authority Required procedures |
| C14443 | P14443 | CN14443 | Netupitant with Palonosetron | Nausea and vomiting  The treatment must be in combination with dexamethasone, unless contraindicated; AND  The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 14443 |
| C14448 | P14448 | CN14448 | Bimekizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (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 be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; 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.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  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, and the face, hand, foot area diagrams 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. | Compliance with Written Authority Required procedures |
| C14449 | P14449 | CN14449 | Bimekizumab | Severe chronic plaque psoriasis  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  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  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  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  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  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  The treatment must be as systemic monotherapy (other than methotrexate); 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 dermatologist. | Compliance with Authority Required procedures |
| C14453 | P14453 | CN14453 | Ixekizumab | 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 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  (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  (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].  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.  The PASI assessment for 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. | Compliance with Written Authority Required procedures |
| C14454 | P14454 | CN14454 | Risankizumab | 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.  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) 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.  (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  (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  (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].  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.  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. | Compliance with Written Authority Required procedures |
| C14458 | P14458 | CN14458 | Risdiplam | 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  (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)  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;  2 units where (ii) applies;  3 units where (iii) applies;  3 units where (iv) applies. | Compliance with Authority Required procedures |
| C14459 | P14459 | CN14459 | Nusinersen | Spinal muscular atrophy (SMA)  Continuing/maintenance treatment in an adult where treatment was initiated in adulthood  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  The treatment must be occurring within the first 104 weeks from the first administered dose; AND  Patient must not be receiving invasive permanent assisted ventilation 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/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 continuation of existing PBS-subsidised treatment with this drug; AND  Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.  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.  PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.  Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.  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 (HFMSE) 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). | Compliance with Authority Required procedures |
| C14460 | P14460 | CN14460 | Bimekizumab | 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 24 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 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. | Compliance with Written Authority Required procedures |
| C14461 | P14461 | CN14461 | Ixekizumab | 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 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) 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.  (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  (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  (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].  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. | Compliance with Written Authority Required procedures |
| C14462 | P14462 | CN14462 | Secukinumab | 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 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  (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  (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].  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.  The PASI assessment for 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. | Compliance with Written Authority Required procedures |
| C14464 | P14464 | CN14464 | Tildrakizumab | 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.  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) 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.  (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  (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  (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].  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.  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. | Compliance with Written Authority Required procedures |
| C14465 | P14465 | CN14465 | Tildrakizumab | 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 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.  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 PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  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 following  (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].  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.  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. | Compliance with Written Authority Required procedures |
| C14468 | P14468 | CN14468 | Onasemnogene abeparvovec | Spinal muscular atrophy (SMA)  Use in a patient untreated with disease modifying therapies for this condition  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 be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND  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  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 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  Must be treated in a treatment centre that is each of:   (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  Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND  Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of:   (i) nusinersen, (ii) risdiplam;  Patient must be no older than 9 months 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).  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.  Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:  (i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or  (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.  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).  Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient. | Compliance with Authority Required procedures |
| C14469 | P14469 | CN14469 | Onasemnogene abeparvovec | Spinal muscular atrophy (SMA)  Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)  The treatment must be given concomitantly with best supportive care for this condition; AND  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  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  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  Must be treated in a treatment centre that is each of:   (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  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. | Compliance with Authority Required procedures |
| C14470 | P14470 | CN14470 | Trastuzumab deruxtecan | Metastatic (Stage IV) HER2 positive breast cancer  Patient must have evidence of human epidermal growth factor (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) in either the primary tumour/a metastatic lesion - establish this finding once only with the first PBS prescription; AND  The condition must have progressed following treatment with at least one prior HER2 directed regimen for metastatic breast cancer; or  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). | Compliance with Authority Required procedures |
| C14471 | P14471 | CN14471 | 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 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 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  Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 14471 |
| C14472 | P14472 | CN14472 | Fremanezumab | Treatment-resistant migraine  Initial treatment  Must be treated by a neurologist; AND  Patient must not be undergoing concurrent treatment with the following PBS benefits:   (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  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  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  Patient must be appropriately managed by their practitioner for medication overuse headache, prior to initiation of treatment with this drug;  Patient must be at least 18 years of age.  Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.  Patient must have the number of migraine headache days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14472 |
| C14476 | P14476 | CN14476 | Ravulizumab | Paroxysmal nocturnal haemoglobinuria (PNH)  Subsequent Continuing Treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' 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).  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. | Compliance with Authority Required procedures |
| C14477 | P14477 | CN14477 | Ravulizumab | Paroxysmal nocturnal haemoglobinuria (PNH)  Initial treatment - Initial 1 (new patient) induction dose  Patient must not have received prior treatment with this drug for this condition; AND  Patient must have a diagnosis of PNH established by flow cytometry; AND  Patient must have a PNH granulocyte clone size equal to or greater than 10%; AND  Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal; AND  Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; or  Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; 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; 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; 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; 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; or  Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded; 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  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) must be at least 1.5 | Compliance with Authority Required procedures |
| C14483 | P14483 | CN14483 | Adalimumab  Baricitinib  Etanercept  Tocilizumab  Tofacitinib  Upadacitinib | 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-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 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.  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).  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.  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. | Compliance with Written Authority Required procedures |
| C14485 | P14485 | CN14485 | Tocilizumab | 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 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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14485 |
| C14486 | P14486 | CN14486 | Adalimumab  Baricitinib  Etanercept  Tocilizumab  Tofacitinib  Upadacitinib | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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;  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.  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. | Compliance with Written Authority Required procedures |
| C14487 | P14487 | CN14487 | Tocilizumab | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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;  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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14488 | P14488 | CN14488 | Abatacept  Adalimumab  Baricitinib  Etanercept  Golimumab  Tocilizumab  Tofacitinib  Upadacitinib | Severe active rheumatoid arthritis  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  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 Initial 1 (new patient) restriction to complete 16 weeks treatment; or  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  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  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C14489 | P14489 | CN14489 | Tocilizumab | 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.  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.  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 will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised 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 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. | Compliance with Written Authority Required procedures |
| C14491 | P14491 | CN14491 | Tocilizumab | 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 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  (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 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.  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.  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.  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 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. | Compliance with Written Authority Required procedures |
| C14493 | P14493 | CN14493 | Adalimumab  Baricitinib  Certolizumab pegol  Etanercept  Tocilizumab  Tofacitinib | 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  (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 will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised 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 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. | Compliance with Written Authority Required procedures |
| C14496 | P14496 | CN14496 | Adalimumab | 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 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 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.  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  (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 prior treatment must be documented in the patient's medical records.  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.  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.  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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the active joint count, ESR and/or CRP result and date of results;  (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. | Compliance with Authority Required procedures |
| C14498 | P14498 | CN14498 | Adalimumab  Baricitinib  Etanercept  Tocilizumab  Tofacitinib  Upadacitinib | 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 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  (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 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.  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).  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. | Compliance with Written Authority Required procedures |
| C14499 | P14499 | CN14499 | Adalimumab  Baricitinib  Certolizumab pegol  Etanercept  Tocilizumab  Tofacitinib | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14499 |
| C14502 | P14502 | CN14502 | Infliximab | 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 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 22 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, 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 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.  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  (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 prior treatment must be documented in the patient's medical records.  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.  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.  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.  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.  Up to a maximum of 3 repeats will be authorised.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the active joint count, ESR and/or CRP result and date of results;  (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. | Compliance with Authority Required procedures |
| C14504 | P14504 | CN14504 | Infliximab | 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).  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14504 |
| C14505 | P14505 | CN14505 | Infliximab | 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).  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14505 |
| 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 |
| C14508 | P14508 | CN14508 | Etanercept | Severe chronic plaque psoriasis  Completion of course - treatment covering weeks 16 to 24 (Face, hand, foot)  Must be treated by a dermatologist; AND  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  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 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14508 |
| C14509 | P14509 | CN14509 | Etanercept | Severe chronic plaque psoriasis  Completion of course - treatment covering weeks 16 to 24 (Whole body)  Must be treated by a dermatologist; AND  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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14509 |
| C14513 | P14513 | CN14513 | Etanercept | 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  Patient must not receive more than 16 weeks of treatment with this biological medicine 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 documented in the patient's medical records.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website.  The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy  (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.  (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) the PASI score that followed each prior therapy trialled;  (iv) the date the PASI scores were determined.  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  (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) the PASI score that followed each prior therapy trialled;  (iv) the date the PASI scores were determined.  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. | Compliance with Authority Required procedures |
| C14515 | P14515 | CN14515 | Infliximab | Severe active rheumatoid arthritis  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  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 (in any form) 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; or  Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND  The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; 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  (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 will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised 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 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.  At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. | Compliance with Written Authority Required procedures |
| C14519 | P14519 | CN14519 | Abatacept  Golimumab | 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; 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 will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised 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 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. | Compliance with Written Authority Required procedures |
| C14522 | P14522 | CN14522 | Abatacept | 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 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 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  (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 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.  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.  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.  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 repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.  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.  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. | Compliance with Written Authority Required procedures |
| C14523 | P14523 | CN14523 | Abatacept | 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; 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 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.  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.  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.  Up to a maximum of 4 repeats will be authorised.  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).  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.  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. | Compliance with Written Authority Required procedures |
| C14524 | P14524 | CN14524 | Abatacept | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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; 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).  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. | Compliance with Written Authority Required procedures |
| C14530 | P14530 | CN14530 | Ravulizumab | Paroxysmal nocturnal haemoglobinuria (PNH)  Grandfather (transition from non-PBS-subsidised treatment)  Patient must have received non-PBS-subsidised treatment with this drug 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 ravulizumab; AND  Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab; AND  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  Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record; AND  Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; 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 ravulizumab; 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 ravulizumab; 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 ravulizumab; 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 ravulizumab; 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 commencing treatment with ravulizumab; 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 commencing treatment with ravulizumab; 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 maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 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)  (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 | Compliance with Authority Required procedures |
| C14531 | P14531 | CN14531 | Ravulizumab | 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 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 maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 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)  (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) | Compliance with Authority Required procedures |
| C14534 | P14534 | CN14534 | Teduglutide | 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  (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.  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).  Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.  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.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); 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 |
| C14538 | P14538 | CN14538 | Tocilizumab | 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-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.  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 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.  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.  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.  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).  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.  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. | Compliance with Written Authority Required procedures |
| C14542 | P14542 | CN14542 | Certolizumab pegol | Severe active rheumatoid arthritis  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  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 Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; or  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  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  The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C14543 | P14543 | CN14543 | Ustekinumab | 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  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) 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.  (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) the PASI score that followed each prior therapy trialled;  (iv) the date the PASI scores were determined.  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  (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) the PASI score that followed each prior therapy trialled;  (iv) the date the PASI scores were determined.  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. | Compliance with Written Authority Required procedures |
| C14544 | P14544 | CN14544 | Infliximab | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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 22 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 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.  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.  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.  Up to a maximum of 3 repeats will be authorised.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the active joint count, ESR and/or CRP result and date of result;  (b) the most recent biological agent and the date of the last continuing prescription.  (c) If applicable, the new baseline scores.  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. | Compliance with Authority Required procedures |
| C14546 | P14546 | CN14546 | Infliximab | 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 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 22 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 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  (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 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.  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.  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.  Up to a maximum of 3 repeats will be authorised.  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 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. | Compliance with Written Authority Required procedures |
| C14547 | P14547 | CN14547 | Infliximab | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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 22 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.  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.  Up to a maximum of 3 repeats will be authorised.  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.  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. | Compliance with Written Authority Required procedures |
| C14548 | P14548 | CN14548 | Infliximab | Severe active rheumatoid arthritis  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  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 Initial 1 (new patient) restriction to complete 22 weeks treatment; or  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  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  The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C14552 | P14552 | CN14552 | Etanercept | Severe chronic plaque psoriasis  Initial 2 treatment (Face, hand, foot) - Change of treatment  Must be treated by a dermatologist; 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 more than once during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction;  Patient must be under 18 years of age.  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 pre-biological treatment baseline values; or  (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.  (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.  In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because  (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.  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. | Compliance with Authority Required procedures |
| C14553 | P14553 | CN14553 | Etanercept | Severe chronic plaque psoriasis  Initial 4 - Re-treatment (Whole body)  Must be treated by a dermatologist; AND  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  Patient must have a documented history of severe chronic plaque psoriasis of the whole body; AND  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:   (i) a disease flare where the PASI score has worsened (increased) by at least 50%, (ii) the current PASI score has returned above 15; AND  Patient must not have failed more than once to achieve an adequate response with etanercept; AND  Patient must not receive more than 16 weeks of treatment with etanercept under this restriction;  Patient must be under 18 years of age.  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. | Compliance with Authority Required procedures |
| C14554 | P14554 | CN14554 | Etanercept | Severe chronic plaque psoriasis  Initial 1 treatment (Face, hand, foot) - 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 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  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  Patient must not receive more than 16 weeks of treatment with etanercept 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 documented in the patient's medical records.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website.  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.  (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);  (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.  Provide in this authority application, and document in the patient's medical records, each of  (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.  (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);  (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.  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  (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);  (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. | Compliance with Authority Required procedures |
| 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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14555 |
| C14556 | P14556 | CN14556 | Golimumab | 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; 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 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.  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).  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.  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. | Compliance with Written Authority Required procedures |
| C14557 | P14557 | CN14557 | Golimumab | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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; 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).  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. | Compliance with Written Authority Required procedures |
| C14558 | P14558 | CN14558 | Ustekinumab | Severe chronic plaque psoriasis  Continuing treatment (Whole body) - 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  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 provided in this application and 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. | Compliance with Authority Required procedures |
| C14560 | P14560 | CN14560 | Abatacept | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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; 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 repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.  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.  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. | Compliance with Written Authority Required procedures |
| C14563 | P14563 | CN14563 | Fremanezumab | Treatment-resistant migraine  Continuing treatment  Must be treated by a neurologist; or  Must be treated by a general practitioner in consultation with a neurologist; AND  Patient must not be undergoing concurrent treatment with the following PBS benefits:   (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  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have achieved and maintained at least 50% reduction from baseline in the number of migraine headache days per month; AND  Patient must continue to be appropriately managed for medication overuse headache.  Patient must have the number of migraine headache days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14563 |
| C14565 | P14565 | CN14565 | Ravulizumab | 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  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  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) must be at least 1.5 | Compliance with Authority Required procedures |
| C14567 | P14567 | CN14567 | Adalimumab | 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).  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14567 |
| C14568 | P14568 | CN14568 | Adalimumab | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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;  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 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.  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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the active joint count, ESR and/or CRP result and date of result;  (b) the most recent biological agent and the date of the last continuing prescription.  (c) If applicable, the new baseline scores.  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. | Compliance with Authority Required procedures |
| C14571 | P14571 | CN14571 | Certolizumab pegol | 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 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 18 to 20 weeks of treatment, depending on the dosage regimen, 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  (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 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.  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).  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. | Compliance with Written Authority Required procedures |
| C14572 | P14572 | CN14572 | Ustekinumab | Severe chronic plaque psoriasis  Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years  Must be treated by a dermatologist; AND  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  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  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  Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; or  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:   (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  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be under 18 years of age.  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.  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). | Compliance with Written Authority Required procedures |
| C14573 | P14573 | CN14573 | Ustekinumab | Severe chronic plaque psoriasis  Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years  Must be treated by a dermatologist; 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 more than once during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be under 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).  Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.  Response to preceding supply  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.  Change in therapy  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  (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  (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.  Recommencing therapy  If the patient is recommencing therapy, in relation to the last administered dose, state whether there was  (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.  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. | Compliance with Written Authority Required procedures |
| C14576 | P14576 | CN14576 | Etanercept | Severe chronic plaque psoriasis  Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years  Must be treated by a dermatologist; AND  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  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  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  Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; or  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:   (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  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction;  Patient must be under 18 years of age.  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. | Compliance with Authority Required procedures |
| C14577 | P14577 | CN14577 | Etanercept | Severe chronic plaque psoriasis  Initial 4 - Re-treatment (face, hand, foot)  Must be treated by a dermatologist; AND  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  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  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:   (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  Patient must not have failed more than once to achieve an adequate response with etanercept; AND  Patient must not receive more than 16 weeks of treatment with etanercept under this restriction;  Patient must be under 18 years of age.  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. | Compliance with Authority Required procedures |
| C14581 | P14581 | CN14581 | Etanercept | 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 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 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.  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  (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 prior treatment must be documented in the patient's medical records.  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.  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.  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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the active joint count, ESR and/or CRP result and date of results;  (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. | Compliance with Authority Required procedures |
| C14582 | P14582 | CN14582 | Etanercept | 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-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).  The assessment of response to treatment must be documented in the patient's medical records.  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 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.  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 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.  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. | Compliance with Authority Required procedures |
| C14583 | P14583 | CN14583 | Abatacept | 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; 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 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.  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 repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14585 | P14585 | CN14585 | Infliximab | 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).  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14585 |
| C14586 | P14586 | CN14586 | Ravulizumab | 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 is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria. | Compliance with Authority Required procedures |
| C14587 | P14587 | CN14587 | Blinatumomab | Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)  Continuing treatment of previously measurable residual disease of Pre-B-cell ALL  Must be treated by a physician experienced in the treatment of haematological malignancies; AND  Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND  Patient must have achieved a complete remission; AND  The condition must be negative for measurable residual disease using the same method used to determine initial PBS eligibility; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND  The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.  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.  An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.  Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.  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. | Compliance with Authority Required procedures |
| C14588 | P14588 | CN14588 | Blinatumomab | Acute lymphoblastic leukaemia  Induction treatment  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  The condition must not be present in the central nervous system or testis; AND  Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND  Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND  Patient must not have received more than 1 line of salvage therapy; AND  The condition must be one of the following:   (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  The condition must have more than 5% blasts in bone marrow; AND  The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.  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.  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.  Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed 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, including what line of salvage; and  (4) if applicable, the date of completion of blinatumomab treatment for measurable residual disease and the date of the patient's subsequent relapse; and  (5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application. | Compliance with Written Authority Required procedures |
| C14590 | P14590 | CN14590 | Adalimumab | 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-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).  The assessment of response to treatment must be documented in the patient's medical records.  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 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.  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 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.  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. | Compliance with Authority Required procedures |
| C14591 | P14591 | CN14591 | Certolizumab pegol | 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 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;  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 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.  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).  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.  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. | Compliance with Written Authority Required procedures |
| C14597 | P14597 | CN14597 | Infliximab | 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).  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.  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.  Up to a maximum of 2 repeats will be authorised.  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 will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised 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 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. | Compliance with Written Authority Required procedures |
| C14600 | P14600 | CN14600 | Etanercept | Severe chronic plaque psoriasis  Initial 2 treatment (Whole body) - Change of treatment  Must be treated by a dermatologist; 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 more than once during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 16 weeks of treatment with this biological medicine under this restriction;  Patient must be under 18 years of age.  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.  In relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because  (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.  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. | Compliance with Authority Required procedures |
| C14603 | P14603 | CN14603 | Etanercept | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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;  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 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.  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 following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the active joint count, ESR and/or CRP result and date of result;  (b) the most recent biological agent and the date of the last continuing prescription.  (c) If applicable, the new baseline scores.  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. | Compliance with Authority Required procedures |
| C14604 | P14604 | CN14604 | Abatacept  Golimumab | 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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14604 |
| C14608 | P14608 | CN14608 | Budesonide | Eosinophilic oesophagitis  Initial treatment - Induction of remission  Patient must have a history of symptoms of oesophageal dysfunction; AND  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  Patient must not receive more than 90 days 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.  Applications for treatment of this condition must be received within 12 weeks of biopsy.  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.  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).  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.  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. | Compliance with Authority Required procedures |
| C14610 | P14610 | CN14610 | Budesonide | Eosinophilic oesophagitis  First continuing treatment - until remission is confirmed  Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND  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. | Compliance with Authority Required procedures |
| C14613 | P14613 | CN14613 | Upadacitinib | 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. | Compliance with Authority Required procedures |
| C14615 | P14615 | CN14615 | Infliximab | 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 22 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 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.  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.  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.  Up to a maximum of 3 repeats will be authorised.  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).  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.  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. | Compliance with Written Authority Required procedures |
| C14617 | P14617 | CN14617 | Abatacept | 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 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 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  (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 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.  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.  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.  Up to a maximum of 4 repeats will be authorised.  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 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. | Compliance with Written Authority Required procedures |
| C14619 | P14619 | CN14619 | Budesonide | Eosinophilic oesophagitis  Subsequent continuing treatment - Maintenance of remission  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  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  The condition must not have progressed while being treated with this drug; 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. | Compliance with Authority Required procedures |
| C14621 | P14621 | CN14621 | Tocilizumab | 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 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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14621 |
| C14622 | P14622 | CN14622 | Certolizumab pegol | Severe active rheumatoid arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more 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 previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; 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  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; 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 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 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. | Compliance with Written Authority Required procedures |
| C14623 | P14623 | CN14623 | Infliximab | 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 22 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).  The assessment of response to treatment must be documented in the patient's medical records.  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 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.  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.  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.  Up to a maximum of 3 repeats will be authorised.  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.  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. | Compliance with Authority Required procedures |
| C14626 | P14626 | CN14626 | Golimumab | 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 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 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  (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 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.  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).  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. | Compliance with Written Authority Required procedures |
| C14628 | P14628 | CN14628 | Ustekinumab | 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  (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 assessment of response to treatment must be provided in this application and documented in the patient's medical records. | Compliance with Authority Required procedures |
| C14629 | P14629 | CN14629 | Etanercept | 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).  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14629 |
| C14631 | P14631 | CN14631 | Blinatumomab | Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)  Initial treatment of measurable residual disease of Pre-B-cell ALL  Must be treated by a physician experienced in the treatment of haematological malignancies; AND  Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND  The condition must not be present in the central nervous system or testis; AND  Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy; AND  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  The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.  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.  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.  An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.  Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.  The authority application must be made in writing and must include  (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.  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. | Compliance with Written Authority Required procedures |
| C14632 | P14632 | CN14632 | Teduglutide | Type III Short bowel syndrome with intestinal failure  Continuing treatment  Must be treated by a gastroenterologist; or  Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit; AND  Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND  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  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  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.  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 volume per week in mL per kg (for a patient yet to turn 18 years of age). State these values in this authority application.  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.  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.  From 1 September 2021  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  (i) a known or estimated retrospective baseline value that would have applied to the patient immediately before commencing treatment with this drug, and  (ii) the current value (observed over a 4 week timeframe)  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.  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.  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.  Patients who do not meet the clinical criteria with respect to demonstrating the minimum reduction in parenteral support must permanently discontinue PBS subsidy.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); 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 |
| C14633 | P14633 | CN14633 | Upadacitinib | 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.  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 will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised 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 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. | Compliance with Written Authority Required procedures |
| C14636 | P14636 | CN14636 | Ustekinumab | Severe chronic plaque psoriasis  Initial 1 treatment (Face, hand, foot) - 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 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  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  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.  (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);  (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.  Provide in this authority application, and document in the patient's medical records, each of  (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.  (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);  (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.  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  (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);  (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. | Compliance with Written Authority Required procedures |
| C14638 | P14638 | CN14638 | Infliximab | 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).  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14638 |
| C14643 | P14643 | CN14643 | Ustekinumab | Severe chronic plaque psoriasis  Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years  Must be treated by a dermatologist; 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 more than once during the current treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be under 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).  Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application.  Response to preceding supply  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.  Change in therapy  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  (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  (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.  Recommencing therapy  If the patient is recommencing therapy, in relation to the last administered dose, state whether there was  (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.  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. | Compliance with Written Authority Required procedures |
| C14647 | P14647 | CN14647 | Tofacitinib | Severe active juvenile idiopathic arthritis  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  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 received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023; AND  Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate prior to initiating treatment with this drug for this condition; or  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:   (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 24 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 methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.  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.  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.  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.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  (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  (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 prior treatment must be documented in the patient's medical records.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) details of prior treatment including dose and duration of treatment.  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.  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. | Compliance with Authority Required procedures |
| C14649 | P14649 | CN14649 | Tofacitinib | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less 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 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; AND  Patient must not receive more than 16 weeks of treatment 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.  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.  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 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.  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. | Compliance with Authority Required procedures |
| C14650 | P14650 | CN14650 | Tofacitinib | 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).  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.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) the date of the last continuing prescription.  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.  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. | Compliance with Authority Required procedures |
| C14652 | P14652 | CN14652 | Tofacitinib | 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 methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.  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.  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.  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.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  (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  (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 prior treatment must be documented in the patient's medical records.  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.  The following information must be provided by the prescriber at the time of application and documented in the patient's medical records  (a) the date of assessment of severe active juvenile idiopathic arthritis; and  (b) details of prior treatment including dose and duration of treatment.  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.  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. | Compliance with Authority Required procedures |
| C14653 | P14653 | CN14653 | Upadacitinib | Severe Crohn disease  Balance of supply for Initial (induction) treatment phases  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  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  The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under. | Compliance with Authority Required procedures |
| C14655 | P14655 | CN14655 | Adalimumab  Etanercept  Golimumab  Ixekizumab  Secukinumab  Tofacitinib  Upadacitinib | 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 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.  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 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.  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 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.  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  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C14656 | P14656 | CN14656 | Adalimumab  Etanercept | 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  (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 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  (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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14659 | P14659 | CN14659 | Certolizumab pegol | 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 to 20 weeks of treatment, depending on the dosage regimen, 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 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 and must be demonstrated at the time of the initial application  (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and  (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.  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.  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.  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 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 completed Exercise Program Self Certification Form included in the supporting information form; and  (iv) baseline ESR and/or CRP level.  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 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. | Compliance with Written Authority Required procedures |
| C14662 | P14662 | CN14662 | Adalimumab  Etanercept  Golimumab  Ixekizumab  Secukinumab  Tofacitinib  Upadacitinib | 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  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  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  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  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  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.  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 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.  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. | Compliance with Written Authority Required procedures |
| C14667 | P14667 | CN14667 | Infliximab | 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  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  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  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  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  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. | Compliance with Authority Required procedures |
| C14668 | P14668 | CN14668 | Infliximab | Ankylosing spondylitis  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  The treatment must have both:   (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  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  (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 an improvement from baseline of at least 2 of the BASDAI and 1 of the following  (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.  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.  All measurements provided must be no more than 1 month old at the time of application. | Compliance with Authority Required procedures |
| C14670 | P14670 | CN14670 | Adalimumab  Etanercept  Golimumab  Ixekizumab  Secukinumab  Tofacitinib  Upadacitinib | 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 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.  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 and must be demonstrated at the time of the initial application  (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and  (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.  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.  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.  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 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 completed Exercise Program Self Certification Form included in the supporting information form; and  (iv) baseline ESR and/or CRP level.  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 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. | Compliance with Written Authority Required procedures |
| C14671 | P14671 | CN14671 | Etanercept | 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  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  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  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  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  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.  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.  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. | Compliance with Authority Required procedures |
| C14672 | P14672 | CN14672 | Adalimumab | 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 5 years or more 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  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  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  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  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  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.  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.  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. | Compliance with Authority Required procedures |
| C14673 | P14673 | CN14673 | Adalimumab  Etanercept | 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 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.  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.  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 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.  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  (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.  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.  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. | Compliance with Authority Required procedures |
| C14676 | P14676 | CN14676 | Nivolumab | Advanced or metastatic gastro-oesophageal cancers  Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND  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  Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first:   (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;  Patient must be in one of the three population subsets described below.  **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  **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  **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 | Compliance with Authority Required procedures - Streamlined Authority Code 14676 |
| C14683 | P14683 | CN14683 | Adalimumab  Etanercept  Infliximab | 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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14683 |
| C14686 | P14686 | CN14686 | Certolizumab pegol | 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  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  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  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  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  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;  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  (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 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.  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. | Compliance with Written Authority Required procedures |
| C14689 | P14689 | CN14689 | Infliximab | 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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14689 |
| C14692 | P14692 | CN14692 | Certolizumab pegol  Golimumab  Ixekizumab  Secukinumab  Tofacitinib  Upadacitinib | Ankylosing spondylitis  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.  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 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  (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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14696 | P14696 | CN14696 | Upadacitinib | Severe Crohn disease  Transitioning from non-PBS to PBS-subsidised supply - 'grandfather' arrangements  Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2023; 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 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  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  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  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  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  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; 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)];  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).  Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following  (a) patient must have evidence of intestinal inflammation;  (b) patient must be assessed clinically as being in a high faecal output state;  (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.  (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.  Evidence of intestinal inflammation includes  (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.  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.  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.  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.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website.  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. | Compliance with Written Authority Required procedures |
| C14697 | P14697 | CN14697 | Tofacitinib | 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.  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.  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 in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14697 |
| C14698 | P14698 | CN14698 | Upadacitinib | Severe Crohn disease  Balance of supply for the Continuing (maintenance) treatment phase  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  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  The treatment must provide no more than the balance available under the treatment phase from which the immediately preceding supply was obtained under. | Compliance with Authority Required procedures |
| C14701 | P14701 | CN14701 | Adalimumab  Etanercept  Infliximab | 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.  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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14701 |
| C14703 | P14703 | CN14703 | Etanercept | Ankylosing spondylitis  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  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  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  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  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. | Compliance with Authority Required procedures |
| 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.  Up to a maximum of 3 repeats will be authorised.  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.  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 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.  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  (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.  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.  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. | Compliance with Authority Required procedures |
| C14708 | P14708 | CN14708 | Durvalumab | Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer)  Patient must have either of the following at treatment initiation:   (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;  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/have been initiated with both:   (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information); AND  Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14708 |
| C14709 | P14709 | CN14709 | Upadacitinib | Severe Crohn disease  Continuing (maintenance) treatment  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 this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  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  Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:   (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;  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).  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  (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. | Compliance with Written Authority Required procedures |
| C14710 | P14710 | CN14710 | Upadacitinib | 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 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 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  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;  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).  Provide at least one of the following  (i) the current Crohn Disease Activity Index (CDAI) score, including the date this score was calculated on;  (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;  (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.  Evidence of intestinal inflammation includes  (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.  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. | Compliance with Written Authority Required procedures |
| C14711 | P14711 | CN14711 | Upadacitinib | Severe Crohn disease  Extended induction period (optional) from weeks 12 to 24  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 experienced an inadequate therapeutic benefit following at least one of:   (i) dosing with 45 mg daily in the initial 12-week induction period, (ii) dosing with 15 mg daily;  Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
| C14713 | P14713 | CN14713 | Adalimumab  Etanercept | 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.  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 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  (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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14714 | P14714 | CN14714 | Certolizumab pegol | 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 to 20 weeks of treatment, depending on the dosage regimen, 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  (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 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.  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 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.  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  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C14715 | P14715 | CN14715 | Etanercept | 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 |
| C14716 | P14716 | CN14716 | Infliximab | 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.  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 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  (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.  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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14718 | P14718 | CN14718 | Infliximab | 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.  Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.  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.  If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.  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.  All relevant details must be documented in the patient's medical records.  The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application  (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and  (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.  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.  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.  The following must be provided at the time of application  (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) details of the completed Exercise Program Self Certification Form (commencement and finish date); and  (iv) baseline ESR and/or CRP level.  All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.  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.  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 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. | Compliance with Authority Required procedures |
| C14720 | P14720 | CN14720 | Tofacitinib | Ankylosing spondylitis  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  The condition must be either radiologically (plain X-ray) confirmed:   (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND  Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND  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  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  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 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 have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition  (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and  (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.  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.  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 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 completed Exercise Program Self Certification Form included in the supporting information form; and  (iv) baseline ESR and/or CRP level.  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  (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.  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. | Compliance with Written Authority Required procedures |
| C14721 | P14721 | CN14721 | Upadacitinib | Severe Crohn disease  Initial 1 (induction treatment covering the first 12 weeks in a patient untreated with biological medicine)  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  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  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  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  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  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  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.  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).  Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following  (a) patient must have evidence of intestinal inflammation;  (b) patient must be assessed clinically as being in a high faecal output state;  (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.  (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.  Evidence of intestinal inflammation includes  (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.  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.  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.  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.  Details of the accepted toxicities including severity can be found on the Services Australia website.  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. | Compliance with Written Authority Required procedures |
| C14723 | P14723 | CN14723 | Infliximab | 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.  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  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 14723 |
| C14724 | P14724 | CN14724 | Infliximab | 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  (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 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  (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.  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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C14726 | P14726 | CN14726 | Bimekizumab | Severe chronic plaque psoriasis  Grandfathered patient - Face, hand, foot (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 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  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 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:   (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  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; 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 sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and  (c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  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. | Compliance with Written Authority Required procedures |
| C14727 | P14727 | CN14727 | Pembrolizumab | Stage II or Stage III triple negative breast cancer  The treatment must be initiated in combination with neoadjuvant chemotherapy; AND  The condition must not have progressed/recurred whilst on treatment with this drug; AND  Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction; AND  Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions. or  Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 4 repeat prescriptions. | Compliance with Authority Required procedures - Streamlined Authority Code 14727 |
| C14728 | P14728 | CN14728 | Upadacitinib | Severe Crohn disease  Continuing (maintenance) treatment  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 this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  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  Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:   (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  The condition must have not met the improvements specified above due to the prescribed dose being too low - this authority application seeks higher dosing;  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).  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  (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. | Compliance with Written Authority Required procedures |
| C14729 | P14729 | CN14729 | Zoledronic acid | Adjuvant management of breast cancer  Patient must be post-menopausal;  Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months. | Compliance with Authority Required 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  (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).  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  (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; or  (iii) confirmation that a severe intolerance occurred that resulted in the cessation of treatment. | Compliance with Written Authority Required procedures |
| C14735 | P14735 | CN14735 | Zoledronic acid | Adjuvant management of breast cancer  Patient must be post-menopausal;  Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months. | Compliance with Authority Required procedures - Streamlined Authority Code 14735 |
| C14737 | P14737 | CN14737 | 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.  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 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.  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.  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 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.  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  (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.  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.  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. | Compliance with Written Authority Required procedures |
| C14741 | P14741 | CN14741 | Olaparib | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer  Initial first-line maintenance therapy (BRCA1/2 gene mutation)  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  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  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  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.  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.  Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing. | Compliance with Authority Required procedures |
| C14742 | P14742 | CN14742 | Olaparib | 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)  Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; 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. | Compliance with Authority Required procedures |
| C14744 | P14744 | CN14744 | Ravulizumab | Atypical haemolytic uraemic syndrome (aHUS)  Switch from PBS-subsidised eculizumab (all phases) - loading dose  Patient must have previously received PBS-subsidised eculizumab under the 'Initial treatment' restriction for this condition; or  Patient must have previously received PBS-subsidised eculizumab under the 'Continuing treatment' restriction for this condition; or  Patient must have previously received PBS-subsidised eculizumab under the 'Extended continuing treatment' restriction for this condition; or  Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition; or  Patient must have previously received PBS-subsidised eculizumab under the 'Continuing recommencement of treatment' restriction for this condition; AND  Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; 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.  The application must indicate the most recent treatment phase that the patient is switching from.  For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.  Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.  The authority application must be in writing and must include all of the following  (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. | Compliance with Authority Required procedures |
| C14746 | P14746 | CN14746 | Ravulizumab | Atypical haemolytic uraemic syndrome (aHUS)  Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements  Patient must have previously received non-PBS-subsidised therapy with this drug for this condition; AND  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:   (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  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  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  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.  Evidence of active and progressing TMA is defined by the following  (1) A platelet count of less than 150x10^9/L; and evidence of at least two of the following  (i) presence of schistocytes on blood film;  (ii) low or absent haptoglobin;  (iii) lactate dehydrogenase (LDH) above normal range; or  (2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and  (3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below  (a) kidney impairment as demonstrated by one or more of the following  (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.  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.  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.  Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.  The authority application must be in writing and must include all of the following  (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 two weeks prior to collection of the ADAMTS-13 assay;  (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;  (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;  (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. | Compliance with Authority Required procedures |
| C14747 | P14747 | CN14747 | Ravulizumab | Atypical haemolytic uraemic syndrome (aHUS)  Extended continuing treatment  Patient must have received PBS-subsidised ravulizumab under the continuing treatment phase for this condition; or  Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; or  Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the extended continuing treatment phase for this condition; AND  Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab 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 have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; or  Patient must have severe TMA-related neurological impairment; or  Patient must have severe TMA-related gastrointestinal impairment; or  Patient must have severe TMA-related pulmonary impairment on current objective measurement; or  Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); or  Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with ravulizumab; 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  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  c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.  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.  A treatment failure is defined as a patient who is  (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.  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).  The authority application must be in writing and must include all of the following  (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;  (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;  (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.  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. | Compliance with Authority Required procedures |
| C14748 | P14748 | CN14748 | Ravulizumab | 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 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.  Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. | Compliance with Authority Required procedures |
| C14749 | P14749 | CN14749 | Ravulizumab | Atypical haemolytic uraemic syndrome (aHUS)  Continuing treatment  Patient must have received PBS-subsidised ravulizumab under the initial treatment phase for this condition; or  Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; or  Patient must have received PBS-subsidised ravulizumab under the grandfather restriction for this condition; AND  Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab 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 72 weeks of ravulizumab 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 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  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  c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.  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.  A treatment failure is defined as a patient who is  (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.  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).  The authority application must be in writing and must include all of the following  (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 kidney transplant if applicable (especially if required due to aHUS);  (7) An inclusion of the individual consequences of recurrent disease, if applicable;  (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;  (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;  (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.  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. | Compliance with Authority Required procedures |
| C14750 | P14750 | CN14750 | Eculizumab | 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. | Compliance with Authority Required procedures |
| C14753 | P14753 | CN14753 | Eculizumab | 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  Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing treatment' restriction for this condition; or  Patient must have previously received PBS-subsidised ravulizumab under the 'Extended continuing treatment' restriction for this condition; or  Patient must have previously received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; or  Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing recommencement of treatment' restriction for this condition; or  Patient must have previously received PBS-subsidised ravulizumab under the 'Grandfather (transitioning from non-PBS to PBS-subsidised treatment)' restriction for this condition; AND  Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample; AND  Patient must not receive more than 24 weeks of C5 inhibitor supply for this current treatment phase 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.  The application must indicate the most recent treatment phase that the patient is switching from.  For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.  Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.  The authority application must be in writing and must include all of the following  (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. | Compliance with Authority Required procedures |
| C14754 | P14754 | CN14754 | Eculizumab | 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  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  c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.  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.  A treatment failure is defined as a patient who is  (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.  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).  The authority application must be in writing and must include all of the following  (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 kidney transplant if applicable (especially if required due to aHUS);  (7) An inclusion of the individual consequences of recurrent disease, if applicable;  (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;  (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 eculizumab is severe extra-renal complications that have significantly improved;  (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.  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. | Compliance with Authority Required procedures |
| C14757 | P14757 | CN14757 | Lumacaftor with ivacaftor | 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. | Compliance with Authority Required procedures |
| C14758 | P14758 | CN14758 | Ustekinumab | Complex refractory Fistulising Crohn disease  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 failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle; 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)].  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.  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.  Applications for authorisation must be made in writing and must include  (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) which includes the following  (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and  (ii) details of prior biological medicine treatment including details of date and duration of treatment.  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.  The most recent fistula assessment must be no more than 4 weeks old at the time of application.  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  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.  Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. | Compliance with Written Authority Required procedures |
| C14760 | P14760 | CN14760 | Olaparib | High grade epithelial ovarian, fallopian tube or primary peritoneal cancer  Continuation of subsequent-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 subsequent-line maintenance therapy (BRCA1/2 gene mutation); AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14760 |
| C14761 | P14761 | CN14761 | Olaparib | High grade epithelial ovarian, fallopian tube or primary peritoneal cancer  Initial subsequent-line maintenance therapy (BRCA1/2 gene mutation)  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  The condition must be platinum sensitive; AND  Patient must have received at least two previous platinum-containing regimens; AND  Patient must have relapsed following a previous platinum-containing regimen; AND  Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen; 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.  Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.  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.  Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing. | Compliance with Authority Required procedures |
| C14764 | P14764 | CN14764 | Obinutuzumab | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)  For combination use with acalabrutinib from treatment cycles 2 to 7 inclusive in first-line therapy  The condition must be untreated; AND  The treatment must be in combination with PBS-subsidised acalabrutinib (refer to Product Information for timing of obinutuzumab and acalabrutinib doses). | Compliance with Authority Required procedures - Streamlined Authority Code 14764 |
| C14765 | P14765 | CN14765 | Lumacaftor with ivacaftor | Cystic fibrosis  Initial 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 be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND  The treatment must be given concomitantly with standard therapy for this condition; AND  The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator 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 Authority Application Supporting Information Form; and  (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  (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Authority Required procedures |
| C14770 | P14770 | CN14770 | Pembrolizumab | Stage IIIB, Stage IIIC or Stage IIID malignant melanoma  Initial treatment - 3 weekly treatment regimen  The treatment must be in addition to complete surgical resection; AND  Patient must have a WHO performance status of 1 or less; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have received prior PBS-subsidised treatment for this condition; AND  The treatment must commence within 12 weeks of complete resection; AND  Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised). | Compliance with Authority Required procedures |
| C14776 | P14776 | CN14776 | Venetoclax | Chronic lymphocytic leukaemia (CLL)  Dose titration for relapsed/refractory disease  The condition must have relapsed or be refractory to at least one prior therapy; AND  The treatment must be the sole PBS-subsidised therapy for this condition; 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  Patient must not be undergoing retreatment with this drug where any of:   (i) prior treatment of CLL/SLL with this same drug was unable to prevent disease progression; (ii) 24 months of PBS-subsidised treatment has been administered with this drug for this condition. | Compliance with Authority Required procedures |
| C14778 | P14778 | CN14778 | Olaparib | 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. | Compliance with Authority Required procedures |
| C14780 | P14780 | CN14780 | Ravulizumab | 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 30x10^9/L and a serum creatinine of greater than 150 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.  Evidence of active and progressing TMA is defined by the following  (1) A platelet count of less than 150x10^9/L; and evidence of at least two of the following  (i) presence of schistocytes on blood film;  (ii) low or absent haptoglobin;  (iii) lactate dehydrogenase (LDH) above normal range; or  (2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and  (3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below  (a) kidney impairment as demonstrated by one or more of the following  (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.  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.  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.  Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.  The authority application must be in writing and must include all of the following  (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 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;  (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.  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. | Compliance with Authority Required procedures |
| C14781 | P14781 | CN14781 | Eculizumab | Atypical haemolytic uraemic syndrome (aHUS)  Initial treatment  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 30x10^9/L and a serum creatinine of greater than 150 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 4 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.  Evidence of active and progressing TMA is defined by the following  (1) a platelet count of less than 150x10^9/L; and evidence of two of the following  (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  (a) kidney impairment as demonstrated by one of the following  (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.  OR  (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  (a) kidney impairment as demonstrated by one of the following  (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.  AND  (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below  (a) kidney impairment as demonstrated by one of the following  (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.  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 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.  Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.  The authority application must be in writing and must include all of the following  (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. | Compliance with Authority Required procedures |
| C14783 | P14783 | CN14783 | Lumacaftor with ivacaftor | Cystic fibrosis  Initial 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 be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND  The treatment must be given concomitantly with standard therapy for this condition; AND  Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND  The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition;  Patient must be aged between 6 and 11 years inclusive.  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 Authority Application Supporting Information Form; and  (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  (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Authority Required procedures |
| C14784 | P14784 | CN14784 | Lumacaftor with ivacaftor | 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 aged between 6 and 11 years inclusive.  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. | Compliance with Authority Required procedures |
| C14785 | P14785 | CN14785 | Lumacaftor with ivacaftor | 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 given concomitantly with standard therapy for this condition; AND  The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition;  Patient must be 12 years 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. | Compliance with Authority Required procedures |
| C14786 | P14786 | CN14786 | Pembrolizumab | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma  Continuing treatment - 3 weekly treatment regimen  Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing; AND  Patient must not have experienced disease recurrence; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised). | Compliance with Authority Required procedures |
| C14787 | P14787 | CN14787 | Ustekinumab | Complex refractory Fistulising Crohn disease  Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)  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  Patient must have an externally draining enterocutaneous or rectovaginal fistula; 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)].  Applications for authorisation must be made in writing and must include  (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) 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.  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.  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.  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  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.  Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. | Compliance with Written Authority Required procedures |
| C14788 | P14788 | CN14788 | Acalabrutinib  Ibrutinib  Zanubrutinib | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)  Treatment of relapsed/refractory disease  The condition must have relapsed or be refractory to at least one prior therapy; 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 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  Patient must be undergoing treatment through this treatment phase listing for the first time (initial treatment). or  Patient must be undergoing continuing treatment through this treatment phase listing, with disease progression being absent. | Compliance with Authority Required procedures |
| C14791 | P14791 | CN14791 | Ravulizumab | Atypical haemolytic uraemic syndrome (aHUS)  Recommencement of treatment  Patient must have demonstrated treatment response to previous treatment with a PBS-subsidised 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 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 10^9/L); OR (iii) TMA-related organ impairment including on recent biopsy; 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  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  c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.  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.  A treatment failure is defined as a patient who is  (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.  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).  The authority application must be in writing and must include all of the following  (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 following the treatment break, 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 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;  (10) Evidence that the patient has had a treatment response to their previous treatment with a C5 inhibitor;  (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;  (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.  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. | Compliance with Authority Required procedures |
| C14792 | P14792 | CN14792 | Eculizumab | Atypical haemolytic uraemic syndrome (aHUS)  Initial treatment - Balance of Supply  Patient must have received PBS-subsidised initial supply of eculizumab for this condition; AND  Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample; 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.  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 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. | Compliance with Authority Required procedures |
| C14793 | P14793 | CN14793 | Eculizumab | 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  c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.  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.  A treatment failure is defined as a patient who is  (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.  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).  The authority application must be in writing and must include all of the following  (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 recommencing eculizumab 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, if applicable;  (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;  (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 eculizumab is severe extra-renal complications that have significantly improved;  (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.  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. | Compliance with Authority Required procedures |
| C14796 | P14796 | CN14796 | Lumacaftor with ivacaftor | Cystic fibrosis  Initial 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 be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND  The treatment must be given concomitantly with standard therapy for this condition; AND  Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND  The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition;  Patient must be 12 years 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 Authority Application Supporting Information Form; and  (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  (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Authority Required procedures |
| C14797 | P14797 | CN14797 | Ravulizumab | 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  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  c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.  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.  A treatment failure is defined as a patient who is  (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.  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).  The authority application must be in writing and must include all of the following  (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 recommencing 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, if applicable;  (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;  (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;  (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.  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. | Compliance with Authority Required procedures |
| C14799 | P14799 | CN14799 | Eculizumab | 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 10^9/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  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  c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.  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.  A treatment failure is defined as a patient who is  (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.  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).  The authority application must be in writing and must include all of the following  (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 following the treatment break, 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 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;  (10) Evidence that the patient has had a treatment response to their previous treatment with eculizumab;  (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;  (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. | Compliance with Authority Required procedures |
| C14801 | P14801 | CN14801 | Ustekinumab | Complex refractory Fistulising Crohn disease  Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply  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  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; 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)]. | Compliance with Authority Required procedures |
| C14802 | P14802 | CN14802 | Ustekinumab | 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  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  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.  The most recent fistula assessment must be no more than 1 month old at the time of application. | Compliance with Authority Required procedures |
| C14805 | P14805 | CN14805 | Eculizumab | Atypical haemolytic uraemic syndrome (aHUS)  Extended Continuing treatment  Patient must have received PBS-subsidised eculizumab under the continuing 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; or  Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the extended 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 have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; or  Patient must have severe TMA-related neurological impairment; or  Patient must have severe TMA-related gastrointestinal impairment; or  Patient must have severe TMA-related pulmonary impairment on current objective measurement; or  Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); or  Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab; 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  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  c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.  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.  A treatment failure is defined as a patient who is  (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.  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).  The authority application must be in writing and must include all of the following  (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 eculizumab 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;  (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;  (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.  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. | Compliance with Authority Required procedures |
| C14806 | P14806 | CN14806 | Ustekinumab | Complex refractory Fistulising Crohn disease  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  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. | Compliance with Authority Required procedures |
| C14808 | P14808 | CN14808 | Ipilimumab | 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.  Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.  Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 14808 |
| C14812 | P14812 | CN14812 | Nivolumab with relatlimab | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment  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  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  Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND  The condition must not be uveal melanoma; AND  The treatment must be the sole PBS-subsidised therapy for this condition;  Patient must weigh 40 kg or more;  Patient must be at least 12 years of age. | Compliance with Authority Required procedures - Streamlined Authority Code 14812 |
| C14813 | P14813 | CN14813 | Tebentafusp | Advanced (unresectable or metastatic) uveal melanoma  Initial treatment - day 1  Patient must have HLA-A\*02:   01-positive disease; AND  Patient must have uveal melanoma that has been confirmed either (i) histologically, (ii) cytologically; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have received prior systemic therapy for metastatic disease;  Patient must be at least 18 years of age.  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. | Compliance with Authority Required procedures |
| C14815 | P14815 | CN14815 | Nivolumab with relatlimab | Unresectable Stage III or Stage IV malignant melanoma  Continuing treatment  Patient must have previously received 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 not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14815 |
| C14816 | P14816 | CN14816 | Nivolumab | Unresectable Stage III or Stage IV malignant melanoma  Initial 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 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  The treatment must be the sole PBS-subsidised therapy for this condition.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14816 |
| C14817 | P14817 | CN14817 | Pembrolizumab | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment - 6 weekly treatment regimen  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 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  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a total of 3 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14817 |
| C14818 | P14818 | CN14818 | Pembrolizumab | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment - 3 weekly treatment regimen  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 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  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a total of 6 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14818 |
| C14819 | P14819 | CN14819 | Nivolumab with relatlimab | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment  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  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  Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND  The condition must not be uveal melanoma; AND  The treatment must be the sole PBS-subsidised therapy for this condition;  Patient must weigh 40 kg or more;  Patient must be at least 12 years of age. | Compliance with Authority Required procedures - Streamlined Authority Code 14819 |
| C14821 | P14821 | CN14821 | Tebentafusp | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14821 |
| C14825 | P14825 | CN14825 | Tebentafusp | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14825 |
| C14828 | P14828 | CN14828 | Fluoxetine | Obsessive-compulsive disorder  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. |  |
| C14829 | P14829 | CN14829 | Nivolumab with relatlimab | Unresectable Stage III or Stage IV malignant melanoma  Continuing treatment  Patient must have previously received 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 not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14829 |
| C14830 | P14830 | CN14830 | Nivolumab | 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 ipilimumab as induction for this condition.  Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.  Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. | Compliance with Authority Required procedures - Streamlined Authority Code 14830 |
| 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 - 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  Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14857 |
| C14858 | P14858 | CN14858 | Linagliptin  Saxagliptin  Sitagliptin | 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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14858 |
| C14859 | P14859 | CN14859 | Dapagliflozin  Empagliflozin | 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 dipeptidyl peptidase 4 inhibitor (gliptin); 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 14859 |
| C14862 | P14862 | CN14862 | Alogliptin | 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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14862 |
| 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  Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 14876 |
| C14878 | P14878 | CN14878 | Dapagliflozin with metformin  Empagliflozin 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 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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14878 |
| C14881 | P14881 | CN14881 | Dapagliflozin with metformin  Empagliflozin 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 insulin; 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14881 |
| C14883 | P14883 | CN14883 | Tiagabine  Zonisamide | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14883 |
| C14885 | P14885 | CN14885 | Empagliflozin with linagliptin  Saxagliptin with dapagliflozin | 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  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 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  (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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14888 |
| C14891 | P14891 | CN14891 | Linagliptin with metformin  Saxagliptin with metformin  Sitagliptin 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 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 14891 |
| C14894 | P14894 | CN14894 | Linagliptin 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 insulin; 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14894 |
| C14895 | P14895 | CN14895 | Tamoxifen | 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. |  |
| C14898 | P14898 | CN14898 | 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  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14898 |
| C14901 | P14901 | CN14901 | Topiramate | Migraine  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; AND  Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months; AND  Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; or  Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker; AND  Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk. or  Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.  Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 14901 |
| C14903 | P14903 | CN14903 | Vigabatrin | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14903 |
| C14905 | P14905 | CN14905 | 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; 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.  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 triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14905 |
| C14911 | P14911 | CN14911 | Linagliptin  Saxagliptin  Sitagliptin | 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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14911 |
| C14912 | P14912 | CN14912 | Testosterone | Androgen deficiency  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND  Patient must not have an established pituitary or testicular disorder; AND  The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs;  Patient must be aged 40 years or older;  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.  Androgen deficiency is defined as  (i) testosterone level of less than 6 nmol per litre; OR  (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 eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).  Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.  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.  The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C14913 | P14913 | CN14913 | Testosterone | Micropenis  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 |
| 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  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 14924 |
| 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 |
| 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  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  (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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14949 |
| C14950 | P14950 | CN14950 | Linagliptin  Sitagliptin | 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 insulin; 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14950 |
| 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  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 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;  Patient must be refractory to an enuresis alarm. | Compliance with Authority Required procedures - Streamlined Authority Code 14972 |
| C14973 | P14973 | CN14973 | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 14973 |
| C14974 | P14974 | CN14974 | 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 insulin; 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14974 |
| C14978 | P14978 | CN14978 | 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; 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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14978 |
| 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  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  Patient must be unable to take a solid dose form of levetiracetam; AND  The treatment must not be given concomitantly with brivaracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 14988 |
| C14989 | P14989 | CN14989 | Tamoxifen | Reduction of breast cancer risk  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 moderate or high risk of developing breast cancer; AND  The treatment must not exceed a dose of 20 mg per day; AND  The treatment must not exceed a lifetime maximum of 5 years for this condition. |  |
| C14990 | P14990 | CN14990 | Medroxyprogesterone | Endometrial cancer  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| C14992 | P14992 | CN14992 | Exemestane | 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. |  |
| C14993 | P14993 | CN14993 | Alendronic acid with colecalciferol | 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.  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 14993 |
| 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.  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 14999 |
| C15000 | P15000 | CN15000 | 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 insulin; 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 15000 |
| C15001 | P15001 | CN15001 | Pioglitazone | 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 a contraindication to a combination of metformin and a sulfonylurea; or  Patient must not have tolerated a combination of metformin and 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 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 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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 15001 |
| C15002 | P15002 | CN15002 | Pioglitazone | 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 insulin; 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. 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 insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 15002 |
| 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  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 15011 |
| C15012 | P15012 | CN15012 | Desmopressin | Cranial diabetes insipidus  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 15012 |
| C15014 | P15014 | CN15014 | Pioglitazone | 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 maximally tolerated doses of metformin and 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 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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 15014 |
| C15015 | P15015 | CN15015 | Testosterone | Androgen deficiency  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 an established pituitary or testicular disorder; AND  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 |
| C15017 | P15017 | CN15017 | 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 radiotherapy for this condition with incomplete resolution. |  |
| C15018 | P15018 | CN15018 | Dutasteride | 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; AND  The treatment must be in combination with an alpha-antagonist. | Compliance with Authority Required procedures - Streamlined Authority Code 15018 |
| C15024 | P15024 | CN15024 | Alendronic acid with colecalciferol | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 15024 |
| C15025 | P15025 | CN15025 | 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 15025 |
| C15028 | P15028 | CN15028 | Bromocriptine | Parkinson disease  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| C15030 | P15030 | CN15030 | Medroxyprogesterone | Endometriosis  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| C15031 | P15031 | CN15031 | Exemestane | Metastatic (Stage IV) 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; AND  The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND  Patient must be receiving PBS-subsidised everolimus concomitantly for this condition;  Patient must not be pre-menopausal. |  |
| C15032 | P15032 | CN15032 | Alendronic acid with colecalciferol | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 15032 |
| C15035 | P15035 | CN15035 | Alendronic acid with colecalciferol | 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.  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 15035 |
| C15036 | P15036 | CN15036 | Tobramycin | Proven Pseudomonas aeruginosa infection  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 cystic fibrosis; AND  Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules; AND  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);  Patient must be 6 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 15036 |
| C15038 | P15038 | CN15038 | 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 condition must be severe hypothyroidism; AND  The treatment must be for initiation of therapy only. | Compliance with Authority Required procedures - 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  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  Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15047 |
| C15049 | P15049 | CN15049 | Nirmatrelvir and ritonavir | SARS-CoV-2 infection  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 both:   (i) at least 50 years of age, (ii) at high risk.  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  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.  Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.  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.  Access to this drug through this restriction is permitted irrespective of vaccination status.  Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.  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.  This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | Compliance with Authority Required procedures - Streamlined Authority Code 15049 |
| C15050 | P15050 | CN15050 | Molnupiravir | SARS-CoV-2 infection  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 not require hospitalisation for COVID-19 infection at the time of prescribing; AND  The treatment must be initiated within 5 days of symptom onset; or  The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic;  Patient must be at least 70 years of age.  Access to this drug through this restriction is permitted irrespective of vaccination status.  Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.  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.  This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.  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.  Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15050 |
| C15051 | P15051 | CN15051 | Dapagliflozin  Empagliflozin | Chronic heart failure  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 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  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  Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 15051 |
| C15055 | P15055 | CN15055 | Molnupiravir | SARS-CoV-2 infection  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:   (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.  For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions  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.  Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.  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.  Access to this drug through this restriction is permitted irrespective of vaccination status.  Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.  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.  This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.  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.  Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15055 |
| C15056 | P15056 | CN15056 | Molnupiravir | SARS-CoV-2 infection  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 both:   (i) at least 50 years of age, (ii) at high risk.  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  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.  Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.  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.  Access to this drug through this restriction is permitted irrespective of vaccination status.  Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.  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.  This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.  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.  Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15056 |
| C15062 | P15062 | CN15062 | Molnupiravir | SARS-CoV-2 infection  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  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  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.  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; OR  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.  a. Chemotherapy or whole body radiotherapy,  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,  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),  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  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.  Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records  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.  Access to this drug through this restriction is permitted irrespective of vaccination status.  Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.  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.  This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.  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.  Details/reasons of contraindications to nirmatrelvir (&) ritonavir must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15062 |
| C15063 | P15063 | CN15063 | Cemiplimab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing treatment - 3 weekly treatment regimen  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 not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first. | Compliance with Authority Required procedures - Streamlined Authority Code 15063 |
| C15065 | P15065 | CN15065 | Inclisiran | Familial heterozygous hypercholesterolaemia  Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication  Patient must have previously received PBS-subsidised treatment with this drug for this condition; or  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  The treatment must be in conjunction with 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. | Compliance with Authority Required procedures - Streamlined Authority Code 15065 |
| C15066 | P15066 | CN15066 | Nusinersen | Pre-symptomatic spinal muscular atrophy (SMA)  Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 1 or 2 copies of the SMN2 gene - Loading doses  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 be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND  The treatment must be given concomitantly with best supportive care for this condition; AND  The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; 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  (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) | Compliance with Authority Required procedures |
| 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  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;  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 risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required. | Compliance with Authority Required procedures |
| C15070 | P15070 | CN15070 | Lacosamide | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures  Must be treated by a neurologist; or  Must be treated by a paediatrician; or  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  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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 15070 |
| C15071 | P15071 | CN15071 | Golimumab | Non-radiographic axial spondyloarthritis  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 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 duration 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. | Compliance with Authority Required procedures |
| C15077 | P15077 | CN15077 | Alirocumab  Evolocumab | Familial heterozygous 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 15077 |
| C15079 | P15079 | CN15079 | Evolocumab | Non-familial hypercholesterolaemia  Initial treatment  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  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 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.  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.  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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.  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  (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. | Compliance with Authority Required procedures |
| 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 with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug; AND  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  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.  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.  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.  Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above. | Compliance with Authority Required procedures |
| C15085 | P15085 | CN15085 | Tebentafusp | Advanced (unresectable or metastatic) uveal melanoma  Continuing treatment  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; or  Patient must have previously received inpatient treatment with this drug for this condition in the public hospital setting; AND  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.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 15085 |
| C15089 | P15089 | CN15089 | Lacosamide | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures  The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND  Must be treated by a neurologist; or  Must be treated by a paediatrician; or  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  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  The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced. | Compliance with Authority Required procedures - Streamlined Authority Code 15089 |
| C15092 | P15092 | CN15092 | Evolocumab | Familial heterozygous hypercholesterolaemia  Initial treatment  The treatment must be in conjunction with dietary therapy and exercise; AND  The condition must have been confirmed by genetic testing; or  The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND  Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; or  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 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 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.  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.  The following must be stated at the time of application and documented in the patient's medical records  (i) the qualifying Dutch Lipid Clinic Network Score; or  (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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. | Compliance with Authority Required procedures |
| C15094 | P15094 | CN15094 | Cemiplimab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment - 3 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 7 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 15094 |
| C15095 | P15095 | CN15095 | Risdiplam | 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.  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. | Compliance with Authority Required procedures |
| 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  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  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.  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.  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 authority application must be made in writing and must include  (a) a completed authority prescription form(s); 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).  The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C15103 | P15103 | CN15103 | Certolizumab pegol | Non-radiographic axial spondyloarthritis  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 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  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 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. | Compliance with Authority Required procedures |
| C15104 | P15104 | CN15104 | Upadacitinib | 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  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  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.  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.  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 authority application must be made in writing and must include  (a) a completed authority prescription form(s); 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).  The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C15106 | P15106 | CN15106 | Alirocumab | Familial heterozygous hypercholesterolaemia  Initial treatment  The treatment must be in conjunction with dietary therapy and exercise; AND  The condition must have been confirmed by genetic testing; or  The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND  Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; or  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 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.  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 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.  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.  The following must be stated at the time of application and documented in the patient's medical records  (i) the qualifying Dutch Lipid Clinic Network Score; or  (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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. | Compliance with Authority Required procedures |
| C15107 | P15107 | CN15107 | Alirocumab | Non-familial hypercholesterolaemia  Initial treatment  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 2.6 millimoles per litre prior to commencing treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9); 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  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.  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 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.  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.  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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.  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  (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. | Compliance with Authority Required procedures |
| C15108 | P15108 | CN15108 | 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 3 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 with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug; AND  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  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.  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.  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.  Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above. | Compliance with Authority Required procedures |
| C15109 | P15109 | CN15109 | Niraparib | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer  Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules  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  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  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  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.  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.  Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing. | Compliance with Authority Required procedures |
| C15110 | P15110 | CN15110 | Inclisiran | Non-familial hypercholesterolaemia  Continuing treatment with this drug or switching treatment from a monoclonal antibody inhibiting proprotein coverase subtilisin kexin type 9 (PSCK9) for this PBS indication  Patient must have previously received PBS-subsidised treatment with this drug for this condition; or  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  The treatment must be in conjunction with 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. | Compliance with Authority Required procedures - Streamlined Authority Code 15110 |
| C15112 | P15112 | CN15112 | Nusinersen | Spinal muscular atrophy (SMA)  Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 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  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;  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 risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required. | Compliance with Authority Required procedures |
| C15115 | P15115 | CN15115 | Ondansetron | Nausea and vomiting  The condition must be associated with radiotherapy being used to treat malignancy. or  The condition must be associated with cytotoxic chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions. | Compliance with Authority Required procedures - Streamlined Authority Code 15115 |
| C15116 | P15116 | CN15116 | Nusinersen | Pre-symptomatic spinal muscular atrophy (SMA)  Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene - Loading doses  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 be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND  The treatment must be given concomitantly with best supportive care for this condition; AND  The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; 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  (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) | Compliance with Authority Required procedures |
| C15117 | P15117 | CN15117 | Certolizumab pegol | 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  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.  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.  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 authority application must be made in writing and must include  (a) a completed authority prescription form(s); 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).  The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C15118 | P15118 | CN15118 | Fluticasone propionate with salmeterol | Asthma  Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. | Compliance with Authority Required procedures - Streamlined Authority Code 15118 |
| C15122 | P15122 | CN15122 | Inclisiran | Familial heterozygous hypercholesterolaemia  Initial treatment  The treatment must be in conjunction with dietary therapy and exercise; AND  The condition must have been confirmed by genetic testing; or  The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND  Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; or  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 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 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.  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.  The following must be stated at the time of application and documented in the patient's medical records  (i) the qualifying Dutch Lipid Clinic Network Score; or  (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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. | Compliance with Authority Required procedures |
| C15124 | P15124 | CN15124 | Acalabrutinib | 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. | Compliance with Authority Required procedures |
| C15125 | P15125 | CN15125 | Golimumab | 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.  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  (a) a CRP measurement no greater than 10 mg per L; or  (b) a CRP measurement reduced by at least 20% from baseline.  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.  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. | Compliance with Authority Required procedures |
| C15126 | P15126 | CN15126 | Certolizumab pegol | Non-radiographic axial spondyloarthritis  Initial treatment - Initial 2 (Change or re-commencement 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 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.  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.  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.  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  (a) a CRP measurement no greater than 10 mg per L; or  (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. | Compliance with Authority Required procedures |
| C15127 | P15127 | CN15127 | Secukinumab | 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  The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); 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.  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.  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.  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.  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 authority application must be made in writing and must include  (a) a completed authority prescription form(s); 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).  The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C15128 | P15128 | CN15128 | Upadacitinib | Non-radiographic axial spondyloarthritis  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have commenced treatment with this biological medicine for this condition prior to 1 August 2023; AND  The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; 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  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 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.  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.  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.  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 authority application must be made in writing and must include  (a) a completed authority prescription form(s); 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).  The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| C15131 | P15131 | CN15131 | Niraparib | 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) in a patient requiring a daily dose of up to 2 capsules  Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; 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 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response. | Compliance with Authority Required procedures |
| C15132 | P15132 | CN15132 | Inclisiran | Familial heterozygous hypercholesterolaemia  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 April 2024; AND  The treatment must be in conjunction with dietary therapy and exercise; AND  The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; or  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  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  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  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  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  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 prior to initiating non-PBS-subsidised treatment with this drug for this condition; 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 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 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 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.  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.  The following must be stated at the time of application and documented in the patient's medical records  (i) the qualifying Dutch Lipid Clinic Network Score; or  (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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.  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. | Compliance with Authority Required procedures |
| C15133 | P15133 | CN15133 | Acalabrutinib | 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  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. | Compliance with Authority Required procedures |
| C15135 | P15135 | CN15135 | Golimumab | Non-radiographic axial spondyloarthritis  Initial treatment - Initial 2 (Change or re-commencement of treatment after a break 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  The treatment must not exceed a maximum of 16 weeks with this drug 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; 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.  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.  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.  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  (a) a CRP measurement no greater than 10 mg per L; or  (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. | Compliance with Authority Required procedures |
| C15137 | P15137 | CN15137 | Secukinumab | 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.  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.  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  (a) a CRP measurement no greater than 10 mg per L; or  (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.  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. | Compliance with Authority Required procedures |
| C15138 | P15138 | CN15138 | Fluticasone propionate with salmeterol | Asthma  Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. | Compliance with Authority Required procedures - Streamlined Authority Code 15138 |
| C15140 | P15140 | CN15140 | Upadacitinib | 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.  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  (a) a CRP measurement no greater than 10 mg per L; or  (b) a CRP measurement reduced by at least 20% from baseline.  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.  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. | Compliance with Authority Required procedures |
| C15141 | P15141 | CN15141 | Olaparib | 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)  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 with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug; AND  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  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.  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.  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.  Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above. | Compliance with Authority Required procedures |
| C15142 | P15142 | CN15142 | Niraparib | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer  Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules  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 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response. | Compliance with Authority Required procedures |
| C15144 | P15144 | CN15144 | Inclisiran | Non-familial hypercholesterolaemia  Initial treatment  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  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 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 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.  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.  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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.  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  (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. | Compliance with Authority Required procedures |
| C15149 | P15149 | CN15149 | Upadacitinib | 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  The treatment must not exceed a maximum of 16 weeks with this drug 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.  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.  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  (a) a CRP measurement no greater than 10 mg per L; or  (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. | Compliance with Authority Required procedures |
| C15150 | P15150 | CN15150 | Upadacitinib | Non-radiographic axial spondyloarthritis  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 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  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. | Compliance with Authority Required procedures |
| C15153 | P15153 | CN15153 | Inclisiran | Non-familial hypercholesterolaemia  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 April 2024; AND  The treatment must be in conjunction with dietary therapy and exercise; AND  Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition; AND  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  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  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  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  Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; or  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  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  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  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  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  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 prior to initiating non-PBS-subsidised treatment with this drug for this condition; 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 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 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 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal.  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.  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment  (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.  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  (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.  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. | Compliance with Authority Required procedures |
| C15155 | P15155 | CN15155 | Niraparib | 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) in a patient requiring a daily dose of 3 capsules  Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; 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 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response. | Compliance with Authority Required procedures |
| C15158 | P15158 | CN15158 | Secukinumab | Non-radiographic axial spondyloarthritis  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 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  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. | Compliance with Authority Required procedures |
| C15160 | P15160 | CN15160 | Niraparib | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer  Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules  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 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response. | Compliance with Authority Required procedures |
| C15162 | P15162 | CN15162 | Niraparib | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer  Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules  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  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  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  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.  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.  Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing. | 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.

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| **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/m2/day in patients weighing more than 20 kg. |
| V9993 | 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/m2/day in patients weighing more than 20 kg. |
| V10745 | Fentanyl  Methadone | 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). |
| V10747 | Fentanyl  Methadone | 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 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). |
| V10748 | Buprenorphine  Morphine  Oxycodone  Oxycodone with naloxone  Tapentadol  Tramadol | 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 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). |
| V10751 | Fentanyl  Methadone | 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). |
| V10752 | Buprenorphine  Morphine  Oxycodone  Oxycodone with naloxone  Tapentadol  Tramadol | 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). |
| V10755 | Buprenorphine  Morphine  Oxycodone  Oxycodone with naloxone  Tapentadol  Tramadol | 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). |
| V10756 | 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). |
| V10762 | Morphine | 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). |
| V10764 | Codeine  Codeine with paracetamol  Hydromorphone  Morphine  Oxycodone  Tramadol | Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for  (i) severe disabling pain associated with malignant neoplasia; or  (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or  (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  (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  (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.  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). |
| V10765 | Morphine | 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). |
| V10770 | Hydromorphone  Morphine | 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). |
| V10771 | Codeine  Codeine with paracetamol  Oxycodone  Tramadol | 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). |
| V10772 | Codeine  Codeine with paracetamol  Oxycodone  Tramadol | 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). |
| V10775 | Morphine | Authorities for increased maximum quantities and/or repeats must only be considered for  (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  (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  (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.  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). |
| V10777 | Hydromorphone  Morphine | 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). |
| V10814 | 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). |
| 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 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  Methadone | 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). |
| 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. |