National Health (Listing of Pharmaceutical Benefits) Instrument 2024

PB 26 of 2024

made under sections 84AF, 84AK, 85, 85A and 88 of the

National Health Act 1953

Compilation No. 5

Compilation date: 1 September 2024

Includes amendments: F2024L01104

This compilation is in 10 volumes

Volume 1: sections 1–24 and Schedule 1 (Part 1: A–C)
Volume 2: Schedule 1 (Part 1: D–K)
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Volume 4: Schedule 1 (Part 1: Q–Z, Part 2), Schedules 2 and 3
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Volume 9: Schedule 4 (Part 1: C14568–C15832, Part 2)
Volume 10: Schedules 5, 6 and Endnotes

Each volume has its own contents

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About this compilation

This compilation

This is a compilation of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* that shows the text of the law as amended and in force on 1 September 2024 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

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)
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14576	P14576	CN14576	Etanercept	Severe chronic plaque psoriasis Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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:	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 14604

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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 mm^2 hpf; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must 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.	
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	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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 mm^2 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 14629

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must not be 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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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%	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
C14650	P14650	CN14650	Tofacitinib	Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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;	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be 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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Tofacitinib Upadacitinib	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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(2) a 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.	
C14659	P14659	CN14659	Certolizumab pegol	Ankylosing spondylitis Initial treatment - Initial 1 (new patient)	Compliance with Written Authority Required

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND	procedures
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14668	P14668	CN14668	Infliximab	Ankylosing spondylitis Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14670	P14670	CN14670	Adalimumab Etanercept Golimumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Ixekizumab Secukinumab Tofacitinib Upadacitinib	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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 14676

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	
C14683	P14683	CN14683	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;	Compliance with Authority Required procedures - Streamlined Authority Code 14683

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(2) a 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.	
C14696	P14696	CN14696	Upadacitinib	Severe Crohn disease Transitioning from non-PBS to PBS-subsidised supply - 'grandfather'	Compliance with Written Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				arrangements	procedures
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 14697

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C14701	P14701	CN14701	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. 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	Compliance with Authority Required procedures - Streamlined Authority Code 14701

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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;	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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)	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 14760

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 14764

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Product Information for timing of obinutuzumab and acalabrutinib doses).	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				ustekinumab. The most recent fistula assessment must be no more than 1 month old at the time of application.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	Compliance with Authority Required procedures - Streamlined Authority Code 14821

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Positive HLA-A*02 01 assessment must be documented in the patient's medical records.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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;	Compliance with Authority Required procedures - Streamlined Authority Code 14847

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be aged 12 years or older.	
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
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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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
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
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.	Compliance with Authority Required procedures - Streamlined Authority Code 14898

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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
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;	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Detrusor overactivity The condition must be stable for the prescriber to consider the listed maximum	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Propantheline	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
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	Compliance with Authority Required procedures - Streamlined Authority Code 14932

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	
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	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				quantity of this medicine suitable for this patient.	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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	Streamlined Authority Code 14973
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
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	Compliance with Authority Required procedures - Streamlined Authority

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 14993

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	
C14994	P14994	CN14994	Minoxidil	Severe refractory hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be initiated by a consultant physician.	
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

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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
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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	Compliance with Authority Required procedures - Streamlined Authority Code 15035

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.	
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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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:	Compliance with Authority Required procedures - Streamlined Authority Code 15049

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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/m^2), 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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Chronic heart failure The condition must be stable for the prescriber to consider the listed maximum	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Empagliflozin	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.	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)	Compliance with Authority Required procedures - Streamlined Authority Code 15055

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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/m^2) 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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,	Compliance with Authority Required procedures - Streamlined Authority Code 15056

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				6. Obesity (BMI greater than 30 kg/m^2), 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.	
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;	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				or	Code 15062
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 15065

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be 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.	
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
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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
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-	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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-	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received PBS-subsidised treatment with this drug for this condition; 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.	Code 15110
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	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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
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

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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)	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				at weeks 4, 8, 12 and 16. Where increased repeats are sought, the maximum quantity sought must not be greater than 1.	
C15163	P15163	CN15163	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment covering the first 6 treatment cycles Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND The treatment must be initiated in combination with platinum-containing chemotherapy; AND The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; 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 have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.	Compliance with Authority Required procedures - Streamlined Authority Code 15163
C15164	P15164	CN15164	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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not be premenopausal. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15165	P15165	CN15165	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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures
C15167	P15167	CN15167	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	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The 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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15169	P15169	CN15169	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy Initial treatment (covering the first 12 weeks of therapy) Patient must have confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy; AND Patient must have maximal end-diastolic left ventricular wall thickness which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy); AND Patient must have confirmed peak left ventricular outflow tract (LVOT) gradient of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of (a) Valsalva manoeuvre, (b) exercise; AND Patient must have a current left ventricular ejection fraction (LVEF) of no less than 55%; AND Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must be symptomatic with NYHA classes II or III. Must be treated by a cardiologist; OR Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy. Patient must be at least 18 years of age. The authority application must be made in writing and must include all the following: (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). (3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) the left ventricular wall thickness in millimetres (mm). (4) The details of a genotyping test report if the patient had been tested. State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) if a gene has been identified that is associated with HCM; (c) if any first-degree family relative has a confirmed diagnosis of HCM. (5) The details of the LVOT gradient report. State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) the measured LVOT gradient; (c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise). (6) NYHA status.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable. (8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including: (a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective; (b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective; (c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details. All results and reports must be documented in the patient's medical records.	
C15177	P15177	CN15177	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 for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran; 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 15177
C15184	P15184	CN15184	Palbociclib	Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have 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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15186	P15186	CN15186	Abemaciclib	Early breast cancer The treatment must be adjuvant to surgical resection; AND The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be hormone receptor positive; AND The condition must be at high risk of recurrence at treatment initiation with this	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system); AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression; AND The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab. Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15188	P15188	CN15188	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy First continuing treatment (until at least 6 months on optimal dose is achieved) Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; OR Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather treatment restriction if dose titration or 6 months on optimal dose is yet to be achieved; AND Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must have a current left ventricular ejection fraction (LVEF) of no less than	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				50%; AND Patient must be titrating mavacamten treatment until optimal dose is achieved; OR Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response. Must be treated by a cardiologist; OR Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy. The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses. For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.	
C15189	P15189	CN15189	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy Subsequent continuing treatment - Maintenance treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; OR Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather arrangements if at least 6 months on optimal dose is achieved; AND Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%; AND Patient must have demonstrated a response after at least 6 months on the optimal	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				dose of mavacamten treatment defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient. Must be treated by a cardiologist; OR Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.	
C15190	P15190	CN15190	Risankizumab	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C15193	P15193	CN15193	Ondansetron	Nausea and vomiting The condition must be associated with radiotherapy being used to treat malignancy; OR The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.	Compliance with Authority Required procedures - Streamlined Authority Code 15193
C15195	P15195	CN15195	Upadacitinib	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. 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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C15196	P15196	CN15196	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather treatment Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND The condition must be, prior to initiation of non-PBS-subsidised treatment with this drug, unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND The condition must be, prior to initiation of non-PBS-subsidised treatment with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic 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 The treatment must be, at initiation of non-PBS-subsidised treatment with this drug, used in combination with platinum-containing chemotherapy; AND Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 15196

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.	
C15199	P15199	CN15199	Risankizumab	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 28 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 28 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 28 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 28 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 28 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 28 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction. Must be treated by a dermatologist.	
C15201	P15201	CN15201	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 for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran; 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 15201
C15204	P15204	CN15204	Upadacitinib	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. 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
C15205	P15205	CN15205	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.	Code 15205
C15206	P15206	CN15206	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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15209	P15209	CN15209	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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15210	P15210	CN15210	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND Patient must have had confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy prior to commencing non-PBS-subsidised treatment; AND Patient must have had maximal end-diastolic left ventricular wall thickness, prior to commencing non-PBS-subsidised treatment, which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy); AND Patient must have had confirmed peak left ventricular outflow tract (LVOT) gradient, prior to commencing non-PBS-subsidised treatment, of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of: (a) Valsalva manoeuvre; (b) exercise; AND Patient must have had left ventricular ejection fraction (LVEF) of no less than 55% prior to commencing non-PBS-subsidised treatment; AND Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless contraindication/ intolerance present, prior to commencing non-PBS-subsidised treatment; AND Patient must have been symptomatic with NYHA classes II or III prior to commencing non-PBS-subsidised treatment; AND Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy; AND Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%; AND	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have demonstrated a response if received the optimal dose of mavacamten treatment for at least 6 months, defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) LVOT gradient; OR Patient must be receiving mavacamten treatment but have not reached at least 6 months on optimal dose to demonstrate a response as defined above. Must be treated by a cardiologist; OR Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy. Patient must be at least 18 years of age. The authority application must be made in writing and must include all the following: (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). (3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) the left ventricular wall thickness in millimetres (mm). (4) The details of a genotyping test report if the patient had been tested. State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) if a gene has been identified that is associated with HCM; (c) if any first-degree family relative has a confirmed diagnosis of HCM. (5) The details of the LVOT gradient report. State all the following: (a) the date, unique identifying number/code or provider number of the report; (b) the measured LVOT gradient;	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise). (6) NYHA status. (7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable. (8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including: (a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective; (b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective; (c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details. All results and reports must be documented in the patient's medical records.	
C15213	P15213	CN15213	Risankizumab	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 28 weeks of treatment under this restriction. Patient must be at least 18 years of age.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 recommence 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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. 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.	
C15218	P15218	CN15218	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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures
C15219	P15219	CN15219	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;	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15221	P15221	CN15221	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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:	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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. 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.	
C15222	P15222	CN15222	Risankizumab	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 28 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 recommence 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. 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.	
C15223	P15223	CN15223	Risankizumab	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C15229	P15229	CN15229	Risankizumab	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 28 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.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C15233	P15233	CN15233	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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15236	P15236	CN15236	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 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.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C15237	P15237	CN15237	Risankizumab	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 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C15242	P15242	CN15242	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;	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15257	P15257	CN15257	Osimertinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy The treatment must be as monotherapy; 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 treatment with this drug for this condition. Patient must be undergoing continuing treatment with this drug as second-line	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed). PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15261	P15261	CN15261	Alogliptin Linagliptin Saxagliptin Sitagliptin Vildagliptin	Diabetes mellitus type 2 The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15261
C15263	P15263	CN15263	Dulaglutide Semaglutide	Diabetes mellitus type 2 Subsequent PBS-prescriptions for any GLP-1 receptor agonist Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.	Compliance with Authority Required procedures - Streamlined Authority Code 15263
C15265	P15265	CN15265	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 used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15265
C15267	P15267	CN15267	Dapagliflozin with metformin Empagliflozin with metformin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				quantity of this medicine suitable for this patient; AND The condition must be inadequately responsive to metformin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.	Streamlined Authority Code 15267
C15269	C15269	CN15269	Empagliflozin with linagliptin Saxagliptin with dapagliflozin	Diabetes mellitus type 2 The treatment must be in combination with at least metformin; AND The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15269
C15270	C15270	CN15270	Empagliflozin with linagliptin Saxagliptin with dapagliflozin	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 at least metformin; AND The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15270
C15276	P15276	CN15276	Alogliptin with metformin Linagliptin with metformin Saxagliptin with metformin Sitagliptin with metformin Vildagliptin with metformin	Diabetes mellitus type 2 The condition must be inadequately responsive to metformin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15276
C15281	P15281	CN15281	Osimertinib	Stage IB, II or IIIA non-small cell lung cancer Adjuvant therapy Patient must be both: (i) initiating treatment, (ii) untreated with EGFR-TKI for non small cell lung cancer; OR	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 EGFR-TKI at the time this drug was initiated. The treatment must be for the purpose of adjuvant therapy following surgical resection; AND Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material; AND Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be commenced within 26 weeks of surgery; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred. PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15283	P15283	CN15283	Osimertinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy 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; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Patient must be undergoing continuing treatment with this drug as first-line therapy	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed). PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15287	P15287	CN15287	Alogliptin Linagliptin Saxagliptin Sitagliptin 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 used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15287
C15288	P15288	CN15288	Alogliptin with metformin 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 condition must be inadequately responsive to metformin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15288
C15289	P15289	CN15289	Dapagliflozin with metformin Empagliflozin with metformin	Diabetes mellitus type 2 The condition must be inadequately responsive to metformin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15289
C15290	P15290	CN15290	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.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15299	P15299	CN15299	Osimertinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy 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 not have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal. Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors. PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures
C15301	P15301	CN15301	Dulaglutide Semaglutide	Diabetes mellitus type 2 First PBS-prescription for this drug The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin; AND Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor. Patient must not be undergoing concomitant PBS-subsidised treatment for type 2	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.	
C15303	P15303	CN15303	Tafamidis	Transthyretin amyloid cardiomyopathy Second and subsequent PBS-subsidised prescriptions for this drug Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m^2; AND The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure; AND The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device. Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment. Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no). If 'no', continued PBS subsidy is available. If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent. Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available. If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed.	Compliance with Authority Required procedures
C15310	P15310	CN15310	Osimertinib	Stage IB, II or IIIA non-small cell lung cancer Adjuvant therapy	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 EGFR-TKI at the time this drug was initiated. The treatment must be for the purpose of adjuvant therapy following surgical resection; AND Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material; AND Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be commenced within 26 weeks of surgery; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred. PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15311	P15311	CN15311	Dapagliflozin Empagliflozin	Diabetes mellitus type 2 The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15311
C15321	P15321	CN15321	Pioglitazone	Diabetes mellitus type 2	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15326	P15326	CN15326	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. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types. Patient must be at least 18 years of age. For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'. This assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 15326
C15329	P15329	CN15329	Osimertinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy Patient must not have previously received this drug for this condition; AND The treatment must be as monotherapy; AND	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have a WHO performance status of 2 or less; AND The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition; AND Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment. PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15333	P15333	CN15333	Melatonin	Insomnia Initial Patient must have Smith-Magenis Syndrome confirmed by genetic testing; AND The condition must be inadequately responsive to sleep hygiene measures, resulting in the patient experiencing a period of at least 12 consecutive weeks of impaired sleep (see definition of impaired sleep below). Must be treated by a medical practitioner identifying as at least one of: (i) a paediatrician, (ii) a sleep physician, (iii) neurologist, (iv) a psychiatrist, (v) a developmental specialist (see NOTE); this authority approval is being sought by one of these 5 prescriber types. Patient must be at least 2 years of age, but yet to turn 18 years of age, at treatment initiation with this drug. Definition: For the purposes of administering this restriction, Smith-Magenis Syndrome is confirmed by the deletion or variation of the retinoic acid induced 1 (RAI1) gene on chromosome 17p11.2 Definition:For the purposes of administering this restriction, impaired sleep is at least one of:(i) less than 6 hours of continuous sleep on at least 3 occasions over a given 5-day interval; (ii) taking at least half an hour to fall asleep on at least 3 occasions over a given 5-day interval. Prior to seeking authorisation for this pharmaceutical benefit, document the amount of continuous sleep/sleep latency in the patient's medical records for a	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				period of 2 consecutive weeks, but ensure the impairment has been observed for at least 12 consecutive weeks. The documented values (averages) will form baseline measurements upon which the extent of response to treatment is to be considered under the Continuing treatment listing. The observations of continuous sleep/sleep latency may be based on any of the following, including a mix of: patient self-reporting, parental observation, documented medical history, sleep studies conducted by health professionals.	
C15338	P15338	CN15338	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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; 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. 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:	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C15341	P15341	CN15341	Dupilumab	Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine. An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine. At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter. A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. 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: (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and (c) if applicable, the eosinophil count and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (e) if applicable, the IgE result and date; and (f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).	
C15348	P15348	CN15348	Dupilumab	Uncontrolled severe asthma Continuing treatment Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug 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 severe asthma; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be aged 12 years or older. An adequate response to this biological medicine is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5. All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and, for the application for continuing therapy to be processed. The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug. Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				whether the patient demonstrated or sustained an adequate response to treatment. A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle. A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts. At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of 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). The following information must be provided at the time of application and must be documented in the patient's medical records: (a) if applicable, details of maintenance oral corticosteroid dose; and (b) a completed Asthma Control Questionnaire (ACQ-5) score.	
C15355	P15355	CN15355	Buprenorphine 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 5 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 15355
C15356	P15356	CN15356	Buprenorphine	Opioid dependence Must be treated by a health care professional.	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. 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.	procedures - Streamlined Authority Code 15356
C15358	P15358	CN15358	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 5 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 15358
C15362	P15362	CN15362	Tafamidis	Transthyretin amyloid cardiomyopathy First PBS-subsidised prescription for this drug The condition must have documented evidence of transthyretin precursor protein present; AND Patient must have experienced at least one episode of hospitalisation that was a direct result of heart failure; OR Patient must have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement; AND Patient must have/have had New York Heart Association class I heart failure at the time of commencing this drug; OR Patient must have/have had New York Heart Association class II heart failure at the time of commencing this drug; AND Patient must have an end-diastolic interventricular septal wall thickness of at least 12 mm on imaging; AND Patient must have an estimated glomerular filtration rate (eGFR) greater than 25	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				mL/minute/1.73 m2. Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment. 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). Evidence of clinical findings to establish the diagnosis: In this authority application, confirm that there is documented evidence of transthyretin precursor protein through either (1) alone, or, both (2) and (3), from the list below: Confirm the following has been completed: (1) amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry; OR (2) bone scintigraphy with grade 2-3 finding AND (3) Confirm that there are negative results for monoclonal protein on each of the following three tests: (a) serum immunofixation (also known as protein electrophoresis) (b) urine immunofixation (c) serum free light chains blood test State which of (1) to (3) above has been completed, as well as the: (i) date of the finding,	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) imaging/pathology report number/code that links the finding to the patient, (iii) name of the amyloid expert centre in this authority application (if applicable). For end-diastolic interventricular septal wall thickness (at least 12 mm), confirm that: (i) imaging (echocardiogram or magnetic resonance imaging) has been undertaken; and (ii) that the imaging report is stored in the patient's medical records. State the date that the imaging was performed and the thickness (in mm) in this authority application. Where this authority application is to transition a patient from non-PBS-subsidised to PBS-subsidised supply (i.e. a 'grandfathered' patient), confirm the following: (i) the patient's heart failure has not worsened to persistent New York Heart Association Class III/IV heart failure while taking this drug.	
C15363	P15363	CN15363	Melatonin	Insomnia Continuing Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have experienced/maintained a clinically meaningful response (as defined below) to the preceding supply of this drug - document the response improvement in the patient's medical records; AND The treatment must have commenced between the ages of 2 to 17 years inclusive. Must be treated by a medical practitioner identifying as at least one of: (i) a paediatrician, (ii) a sleep physician, (iii) neurologist, (iv) a psychiatrist, (v) a developmental specialist (see NOTE); this authority approval is being sought by one of these 5 prescriber types; 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. Treatment must cease if a patient is unable to achieve a clinically meaningful	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				response on the maximum dose of melatonin specified in the Product Information. Definition: A clinically meaningful response to this drug is defined as at least one of: (i) an increase in total sleep time of at least 45 minutes per night on average from baseline; (ii) a decrease in the time it takes to fall asleep by at least 15 minutes per night on average from baseline.	
C15369	P15369	CN15369	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	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have 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; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; 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. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C15370	P15370	CN15370	Olaparib	Early breast cancer Initial treatment The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND Patient must have received neoadjuvant or adjuvant chemotherapy; AND The treatment must be adjuvant to surgical resection; AND The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND Patient must have received neoadjuvant chemotherapy, and residual invasive cancer is confirmed in the breast and/or resected lymph nodes (pathological complete response was not achieved); OR Patient must have received adjuvant chemotherapy for triple negative breast cancer, and has either: (a) node positive disease is present, (b) a primary tumour greater than 20 mm; OR	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have received adjuvant chemotherapy for hormone receptor positive breast cancer, and has at least 4 positive lymph nodes; AND The treatment must not be a PBS-subsidised benefit beyond the following, whichever comes first: (i) a total of 52 weeks of treatment (including any non-PBS-subsidised supply), (ii) disease recurrence. Mark any remaining repeat prescriptions with the word 'cancelled' where (i)/(ii) has occurred; AND The treatment must be commenced within 12 weeks of completing other therapy noting that other therapy can be any of the following therapy: (i) surgery, (ii) radiotherapy, (iii) chemotherapy; AND The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab. Retain all pathology imaging and investigative test results in the patient's medical records.	
C15371	P15371	CN15371	Olaparib	Early breast cancer Continuing treatment Patient must have received PBS-subsidised treatment with this drug as adjuvant therapy for this condition; AND Patient must not have developed disease recurrence while receiving treatment with this drug for this condition; AND The treatment must not be a PBS-subsidised benefit beyond a total of 52 weeks of treatment (including any non-PBS-subsidised supply); AND The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab.	Compliance with Authority Required procedures
C15385	P15385	CN15385	Buprenorphine	Opioid dependence Must be treated by a health care professional. The treatment must be within a framework of medical, social and psychological treatment. 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 15385

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15391	P15391	CN15391	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 tablets 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
C15395	P15395	CN15395	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	Compliance with Authority Required procedures - Streamlined Authority Code 15395

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; 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. 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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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 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 of 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 Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C15406	P15406	CN15406	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	Compliance with Authority Required procedures - Streamlined Authority Code 15406

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types. Patient must be at least 18 years of age. For patients who do not demonstrate an adequate response to deucravacitinib, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'. This assessment must be documented in the patient's medical records.	
C15407	P15407	CN15407	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 tablets 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
C15408	P15408	CN15408	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 tablets	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. 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.	
C15410	P15410	CN15410	Evolocumab	Familial heterozygous hypercholesterolaemia Initial treatment	Compliance with Authority Required procedures -

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be in conjunction with dietary therapy and exercise; AND	Streamlined Authority Code 15410
				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; OR	
				Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; 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.	
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 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 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. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C15414	P15414	CN15414	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 tablets 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				drug for this condition. 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.	
C15416	P15416	CN15416	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 tablets 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
C15424	P15424	CN15424	Dupilumab	Uncontrolled severe asthma Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR	
				Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND	
				Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR	
				Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND	
				Patient must have a duration of asthma of at least 1 year; AND	
				Patient must have been receiving regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation; AND	
				Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR	
				Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND	
				Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. Optimised asthma therapy includes: (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND (ii) treatment with oral corticosteroids as outlined in the clinical criteria. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. 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 the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter. A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Advice). The following must be provided at the time of application and documented in the patient's medical records: (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (d) Asthma Control Questionnaire (ACQ-5) score; and (e) if applicable, the eosinophil count and date; and (f) if applicable, the IgE result and date.	
C15425	P15425	CN15425	Dupilumab	Uncontrolled severe asthma Initial treatment - Initial 2 (Change of treatment) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR Patient must have each of: (i) total serum human immunoglobulin E of at least 30	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				IU/mL measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, (ii) past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND Patient must have received regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine. An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				biological medicine. At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter. A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts. A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. 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: (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and (c) if applicable, the eosinophil count and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (e) if applicable, the IgE result and date; and (f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).	
C15428	P15428	CN15428	Niraparib	High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 tablets 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.	procedures
C15430	P15430	CN15430	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-	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; 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. 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)).	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C15432	P15432	CN15432	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	Compliance with Authority Required procedures - Streamlined Authority Code 15432

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
				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 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 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 documented in the patient's medical records	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C15433	P15433	CN15433	Dupilumab	Uncontrolled severe asthma Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy) Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma. Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma; AND Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records; AND Patient must have a duration of asthma of at least 1 year; AND Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE; AND Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records; AND Patient must not receive more than 32 weeks of treatment under this restriction; AND The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma. Patient must be aged 12 years or older. Optimised asthma therapy includes: (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. 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 the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator. At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter. A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts. 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: (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				receiving optimised asthma therapy (date and treatment); and (d) Asthma Control Questionnaire (ACQ-5) score; and (e) if applicable, the eosinophil count and date; and (f) if applicable, the IgE result and date.	
C15439	P15439	CN15439	Buprenorphine	Opioid dependence Must be treated by a health care professional. 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. 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 15439
C15440	P15440	CN15440	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 tablets 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;	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. 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.	
C15441	P15441	CN15441	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 tablets 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. 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C15443	P15443	C15443	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; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. 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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C15445	P15445	CN15445	Adalimumab	Vision threatening non-infectious uveitis	Compliance with

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 for this condition; AND The treatment must not exceed 24 weeks under this restriction per authority application. Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; 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. An adequate response to treatment is defined as: (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only) 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.	Authority Required procedures - Streamlined Authority Code 15445
C15446	P15446	CN15446	Adalimumab	Vision threatening non-infectious uveitis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				this condition; AND Patient must demonstrated or sustained an adequate response to treatment with this drug for this condition; AND The treatment must not exceed 24 weeks under this restriction per authority application. Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; 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. An adequate response to treatment is defined as: (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only) 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.	
C15450	P15450	CN15450	Adalimumab	Vision threatening non-infectious uveitis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2024; AND	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist; AND	
				Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent prior to commencing non-PBS-subsidised treatment; OR	
				Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy prior to commencing non-PBS-subsidised treatment; OR	
				Patient must have failed to achieve an adequate response to prior conventional immunomodulatory therapy in patients for whom corticosteroids are not clinically appropriate prior to commencing non-PBS-subsidised treatment; OR	
				Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy prior to commencing non-PBS-subsidised treatment; AND	
				Patient must have demonstrated or sustained an adequate response to treatment with this drug for this condition if they have received more than 25 weeks of non-PBS-subsidised treatment; AND	
				The treatment must not exceed 24 weeks under this restriction.	
				Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; 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.	
				Vision threatening disease is defined as at least 1 of the following:	
				(a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent;	
				(b) A 2-step increase in anterior chamber cells or vitreous haze;	
				(c) New retinal vasculitis;	
				(d) New retinal or choroidal lesions;	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(e) Other signs of disease progression including visual field changes or electroretinogram changes An adequate response to treatment is defined as: (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only)	
C15454	P15454	CN15454	Cabozantinib	Locally advanced or metastatic differentiated thyroid cancer Initial treatment The condition must be refractory to radioactive iodine; OR Patient must be deemed ineligible for treatment with radioactive iodine; AND Patient must have progressive disease according to Response Evaluation Criteria in Solid Tumours (RECIST) whilst on treatment with a vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor (TKI) for this indication; OR Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to prior VEGF-targeted TKI therapy; AND Patient must have a WHO performance status of no higher than 2; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have thyroid stimulating hormone adequately suppressed. Radioactive iodine refractory is defined as: (i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or (ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or	Compliance with Authority Required procedures - Streamlined Authority Code 15454

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(iii) progression within 12 months of a single RAI treatment; or (iv) progression after two RAI treatments administered within 12 months of each other.	
C15455	P15455	CN15455	Atezolizumab	Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,875 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. 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. 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 15455
C15456	P15456	CN15456	Midazolam	Generalized convulsive status epilepticus	Compliance with

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. At the time of the authority application, practitioners should request the appropriate quantity to cater for the patient's circumstances. Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.	Authority Required procedures
C15457	P15457	CN15457	Midazolam	Generalized convulsive status epilepticus Initial treatment Patient must have been assessed to be at significant risk of status epilepticus; AND Patient must have experienced at least one prolonged seizure (greater than 5 minutes duration) requiring emergency medical attention within the previous 5 years. Patient must be at least one year of age. The treatment must initiated by a specialist physician experienced in the treatment of epilepsy. At the time of the authority application, medical practitioners should request the appropriate quantity to cater for the patient's circumstances. Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.	Compliance with Authority Required procedures
C15466	P15466	CN15466	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 The treatment must not be for maintenance therapy post-transplant.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C15467	P15467	CN15467	Larotrectinib	Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion Initial treatment The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence: (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date; AND The condition must be non-small cell lung cancer confirmed through a pathology report from an Approved Pathology Authority (of any date); OR The condition must be soft tissue sarcoma confirmed through a pathology report from an Approved Pathology Authority (of any date); OR The condition must be confirmed through a pathology report from an Approved Pathology Authority (of any date) as either: (i) glioma, (ii) glioneuronal tumour, (iii) glioblastoma; AND The condition must be metastatic disease; OR	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be both: (i) locally advanced, (ii) unresectable; OR	
				The condition must be locally advanced where surgical resection is likely to result in severe morbidity; AND	
				Patient must have received prior systemic treatment for this disease; OR	
				Patient must have a condition that predisposes them to an unacceptable risk of intolerance to other systemic therapies; AND	
				The treatment must be the sole PBS-subsidised anti-cancer therapy for this condition; AND	
				Patient must not receive more than 3 months of treatment under this restriction.	
				Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition.	
				Patient must be at least 18 years of age.	
				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 the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.	
				(b) details of the pathology report establishing the carcinoma type (non-small cell lung cancer, soft tissue sarcoma or either glioma/ glioneuronal tumour/ glioblastoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.	
				(c) details of prior systemic treatment for this disease or details of the condition that predisposes the patient to an unacceptable risk of intolerance to other systemic therapies.	
				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) details of the proposed prescription; 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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Advice).	
C15469	P15469	CN15469	Beclometasone with formoterol	Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy. Patient must be at least 18 years of age.	Compliance with Authority Required procedures - Streamlined Authority Code 15469
C15471	P15471	CN15471	Nivolumab	Resectable non-small cell lung cancer (NSCLC) The condition must be at least one of: (i) node positive, (ii) at least 4 cm in size; AND The treatment must be for neoadjuvant use in a patient preparing for surgical resection; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with platinum-based chemotherapy. Patient must not be undergoing treatment with more than 3 PBS-subsidised doses of this drug per lifetime for this indication. In non-squamous type NSCLC where any of the following is known to be present, this drug must not be a PBS benefit: (i) activating epidermal growth factor receptor (EGFR) gene mutation, (ii) anaplastic lymphoma kinase (ALK) gene rearrangement.	Compliance with Authority Required procedures - Streamlined Authority Code 15471
C15473	P15473	CN15473	Adalimumab	Vision threatening non-infectious uveitis Balance of Supply Patient must have received PBS-subsidised treatment with this drug for this condition; AND Patient must have received insufficient therapy with this drug for this condition to	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				complete one of the following: (i) 25 weeks for initial treatment; (ii) 25 weeks for recommencement treatment; (iii) 24 weeks for continuing treatment; (iv) 24 weeks for transitioning from non-PBS to PBS-subsidised treatment.	
C15474	P15474	CN15474	Adalimumab	Vision threatening non-infectious uveitis Initial treatment Patient must have non-infectious uveitis that is vision threatening with the diagnosis confirmed by an ophthalmologist, rheumatologist, or immunologist; AND Patient must have failed to achieve an adequate response to corticosteroid therapy in combination with at least 1 immunosuppressive agent; OR Patient must have flared when corticosteroid therapy was tapered to a dose of less than or equal to 7.5 mg per day of prednisone or equivalent while on immunomodulatory therapy; OR Patient must have failed to achieve an adequate response to at least one immunosuppressive agent in patients for whom corticosteroids are not clinically appropriate; OR Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to corticosteroid and immunomodulatory therapy; AND The treatment must not exceed 25 weeks under this restriction. Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; 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. Vision threatening disease is defined as at least 1 of the following: (a) A decrease in visual acuity of at least 10 letters using an ETDRS chart or equivalent; (b) A 2-step increase in anterior chamber cells or vitreous haze; (c) New retinal vasculitis; (d) New retinal or choroidal lesions;	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(e) Other signs of disease progression including visual field changes or electroretinogram changes A failure to achieve an adequate response is defined as failure to meet one or more of the below criteria: (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only) Details of prior immunomodulatory agent and corticosteroid treatment, or details of contraindications or developed intolerances necessitating treatment withdrawal, must be documented in the patient's medical record. 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 vision threatening disease. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; 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).	
C15477	P15477	CN15477	Selumetinib	Neurofibromatosis type 1 Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be tolerating treatment; AND	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have achieved either: (i) stabilisation of disease, (ii) adequate response to treatment, if have received at least 12 months of treatment with this drug. Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation. At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) 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. For the purpose of administering this restriction, adequate response is defined as: 1. stability or improvement of the initial baseline measurements prior to initiating treatment with this drug; 2. relevant imaging has not shown an increase in tumour size of 20% or more.	
C15479	P15479	CN15479	Cabozantinib	Locally advanced or metastatic differentiated thyroid cancer Continuing treatment The condition must be refractory to radioactive iodine; OR Patient must be deemed ineligible for treatment with radioactive iodine; AND 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 have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).	Compliance with Authority Required procedures - Streamlined Authority Code 15479
C15485	P15485	CN15485	Avelumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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; 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.	procedures - Streamlined Authority Code 15485
C15489	P15489	CN15489	Adalimumab	Vision threatening non-infectious uveitis Recommencement of treatment Patient must have a documented history of non-infectious uveitis that is vision threatening; 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 prior to having a break in therapy with this drug for this condition; AND The treatment must not exceed 25 weeks under this restriction. Must be treated by an ophthalmologist, rheumatologist or immunologist with expertise in uveitis; 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. An adequate response to treatment is defined as: (a) Sustained reduction in inflammation defined as a 2-step decrease from baseline in Standardisation of Uveitis Nomenclature (SUN) criteria for anterior chamber or vitreous haze; or (b) Sustained quiescence of inflammation defined as Standardisation of Uveitis Nomenclature (SUN) criteria less than or equal to 0.5+ anterior chamber or	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				vitreous haze, absence of active vitreous or retinal lesions or vitreous cells; or (c) Sustained corticosteroid sparing effect, allowing reduction in prednisone to less than 7.5 mg daily; or (d) Reduction in frequency of ocular attacks to less than or equal to 1 per year (patients with Behcet's disease only) 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.	
C15490	P15490	CN15490	Selumetinib	Neurofibromatosis type 1 Initial treatment Patient must have plexiform neurofibroma(s) (PN) that is causing/likely to cause at least one of: (i) significant symptoms/morbidity, (ii) disability, (iii) disfigurement, (iv) impairment of normal body function; AND Patient must have PN for which complete resection cannot be performed; AND Patient must have either a: (i) Karnofsky, (ii) Lansky Performance Score of at least 70%. Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation. Patient must be aged between 2 to 18 years; AND Patient must be able to swallow the whole capsule form of this drug. At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) 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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				documented in the patient's medical records. For the purpose of administering this restriction, significant symptoms/morbidity are defined as, but not limited to: 1. head and neck PN that can compromise the airway or great vessels; 2. paraspinal PN that can cause myelopathy; 3. brachial or lumbar plexus PN that can cause nerve compression and loss of function; 4. PN that can result in major deformity or significant disfiguring (e.g. orbital PN); 5. PN of the extremity that can cause limb hypertrophy or loss of function; and 6. painful PN. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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).	
C15491	P15491	CN15491	Selumetinib	Neurofibromatosis type 1 Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have previously received treatment with this drug for this condition prior to 1 August 2024; OR Patient must have previously received treatment with another mitogen-activated protein kinase (MEK) inhibitor for this condition prior to 1 August 2024; 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-subsidised supply of a MEK inhibitor (including selumetinib) was commenced, the patient: (i) had PN that caused/was likely to cause at least one of: (a) significant symptoms/morbidity, (b) disability, (c) disfigurement, (d) impairment of normal body function; (ii) had PN for which complete PN resection could not be performed either: (a) safely, (b) without causing unacceptable morbidity; (iii) had either a: (a) Karnofsky, (b) Lansky Performance Score of at least 70%; (iv) was aged between	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				2 to 18 years; (v) was able to swallow the whole capsule form if received non-PBS supply with selumetinib; AND	
				Patient must be tolerating treatment; AND	
				Patient must have achieved either: (i) stabilisation of disease, (ii) adequate response to treatment, if have received at least 12 months of treatment.	
				Must be treated by a prescriber who is either: (i) a specialist physician with expertise in neurofibromatosis, (ii) a medical practitioner in consultation with a specialist physician with expertise in neurofibromatosis if attendance is not possible due to geographic isolation.	
				At the time of the authority application, medical practitioners must request the appropriate number of packs of appropriate strength(s) to provide sufficient drug, based on the body surface area (BSA) 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.	
				For the purpose of administering this restriction, significant symptoms/morbidity are defined as, but not limited to:	
				1. head and neck PN that can compromise the airway or great vessels;	
				2. paraspinal PN that can cause myelopathy;	
				3. brachial or lumbar plexus PN that can cause nerve compression and loss of function;	
				4. PN that can result in major deformity or significant disfiguring (e.g. orbital PN);	
				5. PN of the extremity that can cause limb hypertrophy or loss of function; and	
				6. painful PN.	
				For the purpose of administering this restriction, adequate response is defined as:	
				1. stability or improvement of the initial baseline measurements prior to initiating treatment with this drug;	
				2. relevant imaging has not shown an increase in tumour size of 20% or more.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The authority application must be made in writing and must include: (1) details of the proposed prescription; 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).	
C15500	P15500	CN15500	Durvalumab	Unresectable Stage III non-small cell lung cancer Initial treatment Patient must have received platinum based chemoradiation therapy; AND The condition must not have progressed following platinum based chemoradiation therapy; AND Patient must have a WHO performance status of 0 or 1; AND Patient must be untreated with immunotherapy at commencement of this drug; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 15500
C15509	P15509	CN15509	Larotrectinib	Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be either: (i) non-small cell lung cancer, (ii) soft tissue sarcoma, (iii) glioma, (iv), glioneuronal tumour, (v) glioblastoma; AND The treatment must cease to be a PBS benefit upon radiographic progression; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be at least 18 years of age. Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15510	P15510	CN15510	Lenvatinib	Locally advanced or metastatic differentiated thyroid cancer Initial treatment The condition must be refractory to radioactive iodine; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have symptomatic progressive disease prior to treatment; OR Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures; AND Patient must have thyroid stimulating hormone adequately suppressed; AND Patient must be one in whom surgery is inappropriate; AND Patient must not be a candidate for radiotherapy with curative intent; AND Patient must have a WHO performance status of 2 or less. Radioactive iodine refractory is defined as: (i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or (ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or (iii) progression within 12 months of a single RAI treatment; or (iv) progression after two RAI treatments administered within 12 months of each other.	Compliance with Authority Required procedures - Streamlined Authority Code 15510
C15518	P15518	CN15518	Cabozantinib	Locally advanced or metastatic differentiated thyroid cancer Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2024; AND The condition must be refractory to radioactive iodine; OR Patient must be deemed ineligible for treatment with radioactive iodine; AND Patient must have had progressive disease according to Response Evaluation Criteria in Solid Tumours (RECIST) whilst on treatment with a vascular endothelial growth factor (VEGF)-targeted tyrosine kinase inhibitor (TKI) prior to receiving this drug for this indication; OR	Compliance with Authority Required procedures - Streamlined Authority Code 15518

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to prior VEGF-targeted TKI therapy prior to receiving this drug for this indication; AND Patient must have had a WHO performance status of no greater than 2 prior to receiving this drug for this indication; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have thyroid stimulating hormone adequately suppressed. Radioactive iodine refractory is defined as: (i) a lesion without iodine uptake on a radioactive iodine (RAI) scan; or (ii) having received a cumulative RAI dose of greater than or equal to 600 mCi; or (iii) progression within 12 months of a single RAI treatment; or (iv) progression after two RAI treatments administered within 12 months of each other.	
C15526	P15526	CN15526	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; AND The treatment must not be for maintenance therapy post-transplant. 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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15527	P15527	CN15527	Nivolumab	Urothelial carcinoma The treatment must be for each of: (i) adjuvant therapy that is/was initiated within 120 days of radical surgical resection, (ii) muscle invasive type disease, (iii) disease considered to be at high risk of recurrence based on pathologic staging of radical surgery tissue (ypT2-ypT4a or ypN+), but yet to recur, (iv) use as the sole PBS-subsidised anti-cancer treatment for this condition; AND Patient must have received prior platinum containing neoadjuvant chemotherapy; AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1. Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information; 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. An increase in repeat prescriptions, up to a value of 11, may only be sought where the prescribed dosing is 240 mg administered fortnightly.	Compliance with Authority Required procedures
C15530	*P15530*	CN15530	Esomeprazole Lansoprazole Omeprazole Pantoprazole Rabeprazole	Gastro-oesophageal reflux 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 be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.*	*Compliance with Authority Required procedures - Streamlined Authority Code 15530*
C15531	*P15531*	CN15531	Esomeprazole Lansoprazole Omeprazole Pantoprazole	Complex gastro-oesophageal reflux disease (GORD) One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control The condition must be stable for the prescriber to consider the listed maximum	*Compliance with Authority Required procedures*

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Rabeprazole	quantity of this medicine suitable for this patient. Must be treated by a gastroenterologist; OR Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes. The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND Patient must must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing. *Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.*	
C15535	P15535	CN15535	Bisacodyl	Terminal malignant neoplasia	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must identify as Aboriginal or Torres Strait Islander.	
C15536	P15536	CN15536	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. Must be treated by a specialist; OR Must be treated by a consultant physician.	Compliance with Authority Required procedures - Streamlined Authority Code 15536
C15539	P15539	CN15539	Macrogol 3350	Chronic constipation 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 with first line interventions such as bulk-forming agents.	
C15542	P15542	CN15542	Apomorphine	Parkinson disease Maintenance therapy 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 experienced severely disabling motor fluctuations which have not responded to other therapy; AND Patient must have been commenced on treatment in a specialist unit in a hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 15542
C15543	P15543	CN15543	Beclometasone with formoterol and glycopyrronium	Chronic obstructive pulmonary disease (COPD) The condition must be stable for the prescriber to consider the listed maximum	Compliance with Authority Required procedures -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Budesonide with glycopyrronium and formoterol Fluticasone furoate with umeclidinium and vilanterol	quantity of this medicine suitable for this patient; AND Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition. Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.	Streamlined Authority Code 15543
C15546	P15546	CN15546	Fluticasone furoate with vilanterol	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 12 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 15546
C15548	P15548	CN15548	Budesonide with formoterol Fluticasone furoate with vilanterol Fluticasone propionate with salmeterol	Chronic obstructive pulmonary disease (COPD) 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 significant symptoms despite regular beta-2 agonist bronchodilator therapy; AND Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.	Compliance with Authority Required procedures - Streamlined Authority Code 15548
C15550	P15550	CN15550	Escitalopram	Moderate to severe generalised anxiety disorder (GAD) The condition must be stable for the prescriber to consider the listed maximum	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				quantity of this medicine suitable for this patient; AND The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist.	
C15551	P15551	CN15551	Escitalopram	Moderate to severe social anxiety disorder (social phobia, SAD) 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 defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.	
C15553	P15553	CN15553	Desvenlafaxine Mirtazapine Moclobemide Reboxetine Venlafaxine	Major depressive disorders The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15556	P15556	CN15556	Carbomer Hypromellose Hypromellose with dextran Polyethylene glycol 400 with propylene glycol	Severe dry eye syndrome The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15558	P15558	CN15558	Bimatoprost with timolol	Elevated intra-ocular pressure The condition must be stable for the prescriber to consider the listed maximum	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Brimonidine with timolol Brinzolamide with brimonidine Brinzolamide with timolol Dorzolamide with timolol Latanoprost with timolol Travoprost with timolol	quantity of this medicine suitable for this patient; AND The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma; OR Patient must have ocular hypertension.	
C15559	P15559	CN15559	Carbomer Carmellose Hyaluronic acid Hypromellose Paraffin Perfluorohexyloctane Polyethylene glycol 400 with propylene glycol Soy lecithin	Severe dry eye syndrome 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 sensitive to preservatives in multi-dose eye drops.	Compliance with Authority Required procedures - Streamlined Authority Code 15559
C15560	P15560	CN15560	Carbomer Carmellose Carmellose with glycerin Hypromellose Hypromellose with carbomer 980	Severe dry eye syndrome	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Hypromellose with dextran Polyethylene glycol 400 with propylene glycol		
C15564	P15564	CN15564	Levodopa with carbidopa and entacapone	Parkinson disease 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 being treated with levodopa decarboxylase inhibitor combinations; AND Patient must be experiencing fluctuations in motor function due to end-of-dose effect.	
C15565	P15565	CN15565	Levodopa with carbidopa and entacapone	Parkinson disease 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 concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.	
C15566	P15566	CN15566	Tiotropium	Severe asthma 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 experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique; AND The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated. Patient must be at least 18 years of age. Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				equivalent) and a long acting beta-2 agonist.	
C15568	P15568	CN15568	Pramipexole	Parkinson disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15570	P15570	CN15570	Pramipexole	Parkinson disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15572	P15572	CN15572	Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate	Terminal malignant neoplasia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15574	P15574	CN15574	Lansoprazole Omeprazole Pantoprazole Rabeprazole	Gastro-oesophageal reflux disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15575	P15575	CN15575	Omeprazole Pantoprazole	Zollinger-Ellison syndrome The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15577	P15577	CN15577	Budesonide with formoterol	Asthma 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 failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition. Must be treated by a respiratory physician; OR Must be treated by a paediatrician.	Compliance with Authority Required procedures - Streamlined Authority Code 15577

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15578	P15578	CN15578	Budesonide	Severe chronic asthma The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must require long-term steroid therapy; AND Patient must not be able to use other forms of inhaled steroid therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 15578
C15580	P15580	CN15580	Mianserin	Severe depression The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15582	P15582	CN15582	Fluoxetine Fluvoxamine Paroxetine Sertraline	Obsessive-compulsive disorder The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15583	P15583	CN15583	Sertraline	Panic disorder 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 use when other treatments have failed; OR The treatment must be for use when other treatments are inappropriate.	
C15585	P15585	CN15585	Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate	Constipation 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 paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.	
C15586	P15586	CN15586	Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl	Constipation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			sulfoacetate	Patient must be receiving palliative care.	
C15587	P15587	CN15587	Bisacodyl	Constipation 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 long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult. Patient must identify as Aboriginal or Torres Strait Islander.	
C15593	P15593	CN15593	Macrogol 3350	Constipation 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 palliative care.	
C15596	P15596	CN15596	Doxycycline	Bronchiectasis 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 8 years or older.	
C15599	P15599	CN15599	Beclometasone with formoterol	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy. Patient must be at least 18 years of age.	Compliance with Authority Required procedures - Streamlined Authority Code 15599

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15600	P15600	CN15600	Beclometasone	Asthma 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 achieve co-ordinated use of other metered dose inhalers containing this drug	
C15601	P15601	CN15601	Fluticasone furoate with umeclidinium and vilanterol Indacaterol with glycopyrronium and mometasone	Severe asthma 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 experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique. Patient must be at least 18 years of age. Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.	Compliance with Authority Required procedures - Streamlined Authority Code 15601
C15602	P15602	CN15602	Entacapone	Parkinson 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 be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination; AND Patient must be experiencing fluctuations in motor function due to end-of-dose effect.	
C15604	P15604	CN15604	Fluticasone propionate with salmeterol	Asthma 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 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 15604

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be aged 4 years or older.	
C15606	P15606	CN15606	Escitalopram	Moderate to severe generalised anxiety disorder (GAD) 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 defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.	
C15607	P15607	CN15607	Formoterol Salmeterol	Asthma The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must experience frequent episodes of the condition; AND Patient must be currently receiving treatment with oral corticosteroids; OR Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.	
C15608	P15608	CN15608	Levodopa with carbidopa	Parkinson disease 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 one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.	
C15611	P15611	CN15611	Tiotropium	Chronic obstructive pulmonary disease (COPD) The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15615	P15615	CN15615	Budesonide with formoterol	Asthma The condition must be stable for the prescriber to consider the listed maximum	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				quantity of this medicine suitable for this patient; AND Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 12 years or over.	Streamlined Authority Code 15615
C15617	P15617	CN15617	Budesonide with formoterol	Asthma 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 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 15617
C15622	P15622	CN15622	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. 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 treatment must be applied to the scrotum area. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C15623	P15623	CN15623	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.	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be applied to the scrotum area. The name of the specialist must be included in the authority application.	
C15624	P15624	CN15624	Eprosartan 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.	
C15625	P15625	CN15625	Doxycycline	Severe acne The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15629	P15629	CN15629	Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate	Constipation 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 long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.	
C15633	P15633	CN15633	Lansoprazole Omeprazole Pantoprazole Rabeprazole	Scleroderma oesophagus The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15634	P15634	CN15634	Aclidinium Glycopyrronium Umeclidinium	Chronic obstructive pulmonary disease (COPD) The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15635	P15635	CN15635	Fluticasone propionate with formoterol	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 12 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 15635
C15636	P15636	CN15636	Cabergoline	Parkinson disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15639	P15639	CN15639	Escitalopram	Major depressive disorders The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15640	P15640	CN15640	Carmellose Carmellose with glycerin Hypromellose with carbomer 980	Severe dry eye syndrome Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.	
C15642	P15642	CN15642	Montelukast	Asthma First-line prevention 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 2 to 5 years inclusive. The condition must be frequent intermittent; OR The condition must be mild persistent; AND The treatment must be the single preventer agent; AND The treatment must be an alternative to sodium cromoglycate; OR The treatment must be an alternative to nedocromil sodium.	Compliance with Authority Required procedures - Streamlined Authority Code 15642

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15643	P15643	CN15643	Montelukast	Asthma First-line prevention 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 frequent intermittent; OR The condition must be mild persistent; AND The treatment must be the single preventer agent; AND The treatment must be an alternative to sodium cromoglycate; OR The treatment must be an alternative to nedocromil sodium. Patient must be aged 6 to 14 years inclusive.	Compliance with Authority Required procedures - Streamlined Authority Code 15643
C15644	P15644	CN15644	Montelukast	Asthma Prevention of condition 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 exercise-induced; AND The treatment must be as an alternative to adding salmeterol xinafoate; OR The treatment must be an alternative to adding formoterol fumarate; AND The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid; AND Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms. Patient must be aged 6 to 14 years inclusive.	Compliance with Authority Required procedures - Streamlined Authority Code 15644
C15648	C15648	CN15648	Rasagiline	Parkinson disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15649	P15649	CN15649	Rotigotine	Parkinson 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 be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.	
C15653	P15653	CN15653	Indacaterol with mometasone	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 12 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 15653
C15654	P15654	CN15654	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 treatment must be applied to the scrotum area. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C15655	P15655	CN15655	Esomeprazole	Scleroderma oesophagus 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 symptoms which are inadequately controlled using a standard dose proton pump inhibitor.	Compliance with Authority Required procedures
C15656	P15656	CN15656	Beclometasone with	Asthma	Compliance with

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			formoterol	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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 18 years or older.	Authority Required procedures - Streamlined Authority Code 15656
C15657	P15657	CN15657	Minocycline	Severe acne 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 responding to other tetracyclines.	
C15658	P15658	CN15658	Esomeprazole Lansoprazole Omeprazole Pantoprazole Rabeprazole	Scleroderma oesophagus 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 15658
C15659	P15659	CN15659	Doxycycline	Chronic bronchitis 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 8 years or older.	
C15661	P15661	CN15661	Macrogol 3350	Constipation 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 paraplegic, quadriplegic or have severe neurogenic impairment of bowel function; AND The condition must be unresponsive to other oral therapies.	
C15666	P15666	CN15666	Citalopram	Major depressive disorders	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Escitalopram Fluoxetine Fluvoxamine Paroxetine Sertraline	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15669	P15669	CN15669	Escitalopram	Moderate to severe generalised anxiety disorder (GAD) 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 defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.	
C15670	P15670	CN15670	Escitalopram	Moderate to severe generalised anxiety disorder (GAD) 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 defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist.	
C15673	P15673	CN15673	Tetrabenazine	Hyperkinetic extrapyramidal disorders 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 15673
C15675	P15675	CN15675	Rotigotine	Parkinson disease The condition must be stable for the prescriber to consider the listed maximum	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				quantity of this medicine suitable for this patient; AND The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.	
C15678	P15678	CN15678	Omeprazole Pantoprazole	Zollinger-Ellison syndrome 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 15678
C15680	P15680	CN15680	Budesonide with formoterol	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 15680
C15682	P15682	CN15682	Esomeprazole	Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion 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 15682
C15686	P15686	CN15686	Doxycycline	Severe acne The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15688	P15688	PN15688	Macrogol 3350	Constipation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be receiving palliative care.	
C15691	P15691	CN15691	Aclidinium with formoterol Indacaterol with glycopyrronium Tiotropium with olodaterol Umeclidinium with vilanterol	Chronic obstructive pulmonary disease (COPD) 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 COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR Patient must have been stabilised on a combination of a LAMA and a LABA.	Compliance with Authority Required procedures - Streamlined Authority Code 15691
C15692	P15692	CN15692	Fluticasone furoate with vilanterol	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 12 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 15692
C15693	P15693	CN15693	Fluticasone propionate with salmeterol	Asthma 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 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 15693
C15696	P15696	CN15696	Escitalopram	Moderate to severe social anxiety disorder (social phobia, SAD) 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 defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15698	P15698	CN15698	Escitalopram	Moderate to severe social anxiety disorder (social phobia, SAD) 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 defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist.	
C15699	P15699	CN15699	Safinamide	Parkinson 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 be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.	
C15700	P15700	CN15700	Selegiline	Late stage Parkinson 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 be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.	
C15702	P15702	CN15702	Budesonide with formoterol	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.	Compliance with Authority Required procedures - Streamlined Authority Code 15702

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be aged 12 years or over.	
C15704	P15704	CN15704	Esomeprazole	Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion 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 symptoms which are inadequately controlled using a standard dose proton pump inhibitor.	Compliance with Authority Required procedures
C15705	P15705	CN15705	Esomeprazole	Complex gastro-oesophageal reflux disease (GORD) One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Must be treated by a gastroenterologist; OR Must be treated by a surgeon with expertise in the upper gastrointestinal tract. The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing. Check patient adherence to any preceding PPI treatment regimen. Exclude non-	Compliance with Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				adherence as a cause of inadequate control before accessing treatment under this restriction.	
C15707	P15707	CN15707	Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate	Anorectal congenital abnormalities The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15708	P15708	CN15708	Bisacodyl	Constipation 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 long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility. Patient must identify as Aboriginal or Torres Strait Islander.	
C15709	P15709	CN15709	Macrogol 3350	Faecal impaction 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 with first line interventions such as bulk-forming agents.	
C15710	P15710	CN15710	Erythromycin	Severe acne 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 one in which tetracycline therapy is inappropriate.	Compliance with Authority Required procedures - Streamlined Authority Code 15710
C15711	P15711	CN15711	Amantadine	Parkinson disease 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 drug induced.	
C15714	P15714	CN15714	Fluticasone propionate with	Asthma The condition must be stable for the prescriber to consider the listed maximum	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			salmeterol	quantity of this medicine suitable for this patient; AND Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.	procedures - Streamlined Authority Code 15714
C15715	P15715	CN15715	Fluticasone propionate with salmeterol	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. Patient must be aged 4 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 15715
C15719	P15719	CN15719	Riluzole	Amyotrophic lateral sclerosis 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; AND Patient must be ambulatory; OR Patient must not be ambulatory, and must be able to either use upper limbs or to swallow; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure.	Compliance with Authority Required procedures
C15722	P15722	CN15722	Paroxetine	Panic disorder The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15726	P15726	CN15726	Bisacodyl	Anorectal congenital abnormalities The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must identify as Aboriginal or Torres Strait Islander.	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15727	P15727	CN15727	Bisacodyl	Megacolon The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must identify as Aboriginal or Torres Strait Islander.	
C15729	P15729	CN15729	Macrogol 3350	Constipation 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 malignant neoplasia.	
C15730	P15730	CN15730	Macrogol 3350	Constipation 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 paraplegic, quadriplegic or have severe neurogenic impairment of bowel function; AND The condition must be unresponsive to other oral therapies.	
C15734	P15734	CN15734	Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate	Constipation 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 long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.	
C15735	P15735	CN15735	Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate	Megacolon The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15736	P15736	CN15736	Indacaterol	Chronic obstructive pulmonary disease (COPD) The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15739	P15739	CN15739	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. The treatment must be applied to the scrotum area. 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
C15745	P15745	CN15745	Macrogol 3350	Constipation 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 malignant neoplasia.	
C15746	P15746	CN15746	Macrogol 3350	Chronic constipation The condition must be stable for the prescriber to consider the listed maximum	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				quantity of this medicine suitable for this patient; AND The condition must be inadequately controlled with first line interventions such as bulk-forming agents.	
C15747	P15747	CN15747	Macrogol 3350	Faecal impaction 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 with first line interventions such as bulk-forming agents.	
C15751	P15751	CN15751	Escitalopram	Moderate to severe social anxiety disorder (social phobia, SAD) 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 defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.	
C15753	P15753	CN15753	Tiotropium	Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease Long-term maintenance treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15754	P15754	CN15754	Tiotropium	Severe asthma The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.	Compliance with Authority Required procedures - Streamlined Authority Code 15754

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; OR Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated. Patient must be aged 6 to 17 years inclusive. Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative	
C15755	P15755	CN15755	Budesonide with formoterol	Asthma 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 had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy. Patient must be aged 12 years or over.	Compliance with Authority Required procedures - Streamlined Authority Code 15755

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15756	P15756	CN15756	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 treatment must be applied to the scrotum area. The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
C15757	P15757	CN15757	Cabozantinib	Stage IV renal cell carcinoma (RCC) Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for maintenance treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2024; 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 Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 15757
C15759	P15759	CN15759	Alectinib Brigatinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Ceritinib	The treatment must be as monotherapy; 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 an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.	
C15764	P15764	CN15764	Adalimumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application.	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply The authority application must be made in writing and must include: (1) details of the proposed prescription; 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 Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.	
C15765	P15765	CN15765	Adalimumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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 authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under 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. The authority application must be made in writing and must include: (1) details of the proposed prescription; and	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(2) a 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 Hurley stage grading; and (ii) the AN count.	
C15767	P15767	C15767	Secukinumab	Moderate to severe hidradenitis suppurativa Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 16 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. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.	
C15768	P15768	C15768	Secukinumab	Moderate to severe hidradenitis suppurativa 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 had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and 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 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 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	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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) details of the proposed prescription(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: (i) the Hurley stage grading; and (ii) the AN count. Details of two completed prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. This restriction is intended for induction dosing only.	
C15772	P15772	CN15772	Budesonide	Mild to moderate Crohn disease The condition must affect the ileum; OR The condition must affect the ascending colon; OR The condition must affect the ileum and ascending colon. The total duration of therapy should be no more than 10 weeks in any single course.	Compliance with Authority Required procedures - Streamlined Authority Code 15772
C15774	P15774	CN15774	Cabozantinib	Stage IV renal cell carcinoma (RCC) Initial treatment The condition must be each of: (i) classified as having an intermediate to poor survival risk score according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), (ii) untreated with a tyrosine kinase inhibitor; OR Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) despite treatment with a tyrosine kinase	Compliance with Authority Required procedures - Streamlined Authority Code 15774

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				inhibitor, irrespective of the current IMDC survival risk score; AND Patient must have a WHO performance status of 2 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must be undergoing treatment with this drug for the first time at the time of the first PBS prescription.	
C15775	P15775	CN15775	Cabozantinib	Stage IV renal cell carcinoma (RCC) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 15775
C15776	C15776	CN15776	Crizotinib 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 have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) 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)	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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) details of the proposed prescription; 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.	
C15777	P15777	CN15777	Adalimumab	Moderate to severe hidradenitis suppurativa First continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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 Hidradenitis Suppurativa Clinical Response (HiSCR) result.	
C15779	P15779	CN15779	Secukinumab	Moderate to severe hidradenitis suppurativa 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 June 2024; AND Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 16 weeks of treatment if the patient has been treated with this drug for this condition for 16 weeks or longer; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 16 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. Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated. The authority application must be made in writing and must include: (a) details of the proposed prescription; and (b) 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 Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics (v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 16 weeks or more of treatment. 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.	
C15781	C15781	CN15781	Larotrectinib	Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion Continuing treatment Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing for solid tumours (of any type) with confirmed NTRK gene fusion where treatment with this drug is/was initiated in a child; OR Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing for solid tumours (of certain specified types) with confirmed NTRK gene fusion which either includes: (i) mammary analogue secretory carcinoma of the salivary gland, (ii) secretory breast carcinoma. The treatment must cease to be a PBS benefit upon radiographic progression; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.	Compliance with Authority Required procedures
C15782	P15782	CN15782	Ganciclovir Valganciclovir	Cytomegalovirus infection and disease Patient must be a solid organ transplant recipient at risk of cytomegalovirus	Compliance with Authority Required procedures -

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				disease.	Streamlined Authority Code 15782
C15784	P15784	CN15784	Ganciclovir Valganciclovir	Cytomegalovirus infection and disease Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 15784
C15787	P15787	CN15787	Migalastat	Fabry disease Grandfather arrangement (transition from LSDP-funded Fabry disease therapy) Patient must have previously received treatment with this drug for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024; OR Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024; AND Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant prior to commencing treatment with this drug; AND Patient must have/have had an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m^2prior to commencing treatment with this drug. Must be treated by a physician with expertise in the management of Fabry disease. Patient must be at least 12 years of age. 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. Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Advice).	
C15788	P15788	CN15788	Adalimumab	Moderate to severe hidradenitis suppurativa 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. Must be treated by a dermatologist. A maximum of 12 weeks of treatment will be authorised under this restriction.	Compliance with Authority Required procedures
C15795	P15795	CN15795	Adalimumab	Moderate to severe hidradenitis suppurativa 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 had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as:	Compliance with Written Authority Required procedures

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and 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 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 authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under 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. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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 Hurley stage grading; and (ii) the AN count.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
C15796	P15796	CN15796	Adalimumab	Moderate to severe hidradenitis suppurativa Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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 Hidradenitis Suppurativa Clinical Response (HiSCR) result.	Compliance with Written Authority Required procedures
C15797	P15797	CN15797	Adalimumab	Moderate to severe hidradenitis suppurativa Continuing treatment	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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 Hidradenitis Suppurativa Clinical Response (HiSCR) result.	
C15799	P15799	CN15799	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have, at the time of application, a Hurley stage II or III grading with	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				an abscess and inflammatory nodule (AN) count greater than or equal to 3; 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 Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(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: (i) the Hurley stage grading; and	

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Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) the AN count. Details of two completed prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.	
C15800	P15800	CN15800	Ganciclovir Valganciclovir	Cytomegalovirus infection and disease Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 15800
C15801	P15801	CN15801	Migalastat	Fabry disease Continuing treatment Patient must have received prior PBS-subsidised treatment with this drug for this condition; 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 not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by migalastat. Must be treated by a physician with expertise in the management of Fabry disease.	Compliance with Authority Required procedures
C15803	P15803	CN15803	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 an anaplastic lymphoma kinase (ALK) gene	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) 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) details of the proposed prescription; 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.	
C15804	P15804	CN15804	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; AND Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.	Compliance with Authority Required procedures
C15805	P15805	CN15805	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have, at the time of application, a Hurley stage II or III grading with	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				an abscess and inflammatory nodule (AN) count greater than or equal to 3; 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 Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(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: (i) the Hurley stage grading; and	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(ii) the AN count. Details of two completed prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. This restriction is intended for induction dosing only.	
C15806	P15806	CN15806	Secukinumab	Moderate to severe hidradenitis suppurativa 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 had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and 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 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 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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) details of the proposed prescription(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: (i) the Hurley stage grading; and (ii) the AN count. Details of two completed prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.	
C15807	P15807	CN15807	Secukinumab	Moderate to severe hidradenitis suppurativa 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 20 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 20 weeks treatment; OR	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have 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 20 weeks treatment; AND The treatment must provide no more than the balance of up to 20 weeks treatment. Must be treated by a dermatologist.	
C15808	P15808	CN15808	Migalastat	Fabry disease Initial treatment Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity; AND Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant; AND Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m^2; AND Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; OR Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; OR Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imagining (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) Late gadolinium enhancement or a low T1 on cardiac MRI; OR Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				disease as shown on objective testing with no other cause or risk factors identified; OR Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiepileptic medications for peripheral neuropathy; OR Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies. Must be treated by a physician with expertise in the management of Fabry disease. Patient must be at least 12 years of age. If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application. Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records. The authority application must be made in writing and must include: (1) details of the proposed prescription; 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).	
C15810	P15810	CN15810	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity 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 following a minimum of 16 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(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: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. Details of two completed prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C15812	P15812	CN15812	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not receive more than 20 weeks of treatment under this restriction.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a dermatologist. Assessment of disease severity 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 following a minimum of 16 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. The authority application must be made in writing and must include: (1) details of the proposed prescription(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: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. This restriction is intended for induction dosing only. Details of two completed prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				doses of 150 mg and 3 repeats. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C15814	P15814	CN15814	Ganciclovir Valganciclovir	Cytomegalovirus infection and disease Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.	Compliance with Authority Required procedures - Streamlined Authority Code 15814
C15818	P15818	P15818	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) details of the proposed prescription; and	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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). Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15819	P15819	P15819	Trastuzumab emtansine	Early HER2 positive breast cancer Continuing adjuvant 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 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. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	Compliance with Authority Required procedures
C15820	P15820	CN15820	Trastuzumab	Early HER2 positive breast cancer Initial treatment (3 weekly regimen) Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); 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 Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH).	Compliance with Authority Required procedures - Streamlined Authority Code 15820

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15826	P15826	CN15826	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. 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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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). Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15827	P15827	CN15827	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. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	Compliance with Authority Required procedures
C15828	P15828	CN15828	Trastuzumab emtansine	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 condition must have progressed following treatment with pertuzumab and trastuzumab in combination; OR	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab; 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 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. The following information must be provided by the prescriber at the time of application: (a) 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). (b) dates of treatment with trastuzumab and pertuzumab; (c) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or (d) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment. 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. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15831	P15831	CN15831	Trastuzumab	Early HER2 positive breast cancer Initial treatment (weekly regimen) Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND The treatment must not be used in a patient with a left ventricular ejection fraction	Compliance with Authority Required procedures - Streamlined Authority Code 15831

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(LVEF) of less than 45% and/or with symptomatic heart failure; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15832	P15832	CN15832	Trastuzumab deruxtecan	Unresectable and/or metastatic HER2-low breast cancer Patient must have evidence of human epidermal growth factor receptor 2 (HER2)-low disease; AND Patient must have received prior chemotherapy in the metastatic setting; OR Patient must have developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; AND Patient must have received or be ineligible for endocrine therapy in the metastatic setting, if hormone receptor positive; 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. 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:	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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. HER2-low is defined as an immunohistochemical (IHC) score of 1+ or an IHC score of 2+ and a negative result on in situ hybridization (ISH). 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-low status 2) Details of prior drug regimens prescribed for the patient 3) Cardiac function test results Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	

Part 2—Variation rules

2 Variation rules

The following table sets out variation rules for variations codes, for the purposes of sections 15 and 16.

Variation Code	Listed Drug	Variation Rules
V4077	Granisetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V4118	Granisetron Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V4139	Granisetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5618	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5721	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5743	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V5778	Ondansetron	Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.
V7273	Icatibant	Increased maximum quantities will be limited to 12 injections per authority prescription.
V7274	Icatibant	Increased maximum quantities will be limited to 12 injections per authority prescription.
V7433	Axitinib	Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.
V8588	Axitinib	Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.
V9041	Pegvisomant	No increase in the maximum quantity or number of units may be authorised for the loading dose.
V9919	Sodium	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

Clause 2

Variation Code	Listed Drug	Variation Rules
	phenylbutyrate	20 kg and up to 13 g/m^2/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/m^2/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.

Variation Code	Listed Drug	Variation Rules
		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.

Clause 2

Variation Code	Listed Drug	Variation Rules
		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

Variation Code	Listed Drug	Variation Rules
		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

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Variation Code	Listed Drug	Variation Rules
		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

Variation Code	Listed Drug	Variation Rules
		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

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Variation Code	Listed Drug	Variation Rules
		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.

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		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).

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Variation Code	Listed Drug	Variation Rules
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.
V15303	Tafamidis	If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed.

Variation Code	Listed Drug	Variation Rules
V15456	Midazolam	At the time of the authority application, practitioners should request the appropriate quantity to cater for the patient's circumstances. Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.
V15457	Midazolam	At the time of the authority application, medical practitioners should request the appropriate quantity to cater for the patient's circumstances. Up to a maximum of 10 syringes for each prescription can be authorised for patients with high frequency seizures.
V15818	Trastuzumab emtansine	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg
V15819	Trastuzumab emtansine	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg
V15820	Trastuzumab	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg
V15826	Trastuzumab deruxtecan	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg
V15827	Trastuzumab emtansine	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg
V15828	Trastuzumab emtansine	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg
V15831	Trastuzumab	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg
V15832	Trastuzumab deruxtecan	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg
V15818	Trastuzumab emtansine	Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg