# National Health (Listing of Pharmaceutical Benefits) Instrument 2012

**PB 71 of 2012**

made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the

*National Health Act 1953*

## Compilation No. 133

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This compilation is in 7 volumes

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| Volume 1: | sections 1–26 and Schedule 1 (Part 1: A–C) |
| Volume 2: | Schedule 1 (Part 1: D–K) |
| Volume 3: | Schedule 1 (Part 1: L–P) |
| Volume 4: | Schedule 1 (Part 1: Q–Z, Part 2), Schedules 2 and 3 |
| Volume 5: | Schedule 4 (Part 1: A–E) |
| **Volume 6:** | **Schedule 4 (Part 1: F–R)** |
| Volume 7: | Schedule 4 (Part 1: S–Z, Part 3), Schedule 5 and Endnotes |

Each volume has its own contents

Prepared by the Office of Parliamentary Counsel, Canberra

# About this compilation

### This compilation

This is a compilation of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* that shows the text of the law as amended and in force on 1 August 2023 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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 and conditions codes

(sections 10-15,17, 18, 20 and 21)

## Part 1—Circumstances, purposes and conditions

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|---|---|---|---|---|---|
| Famciclovir | C5937 | P5937 | | Recurrent moderate to severe genital herpes<br>Episodic treatment<br>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5937 |
| | C5943 | P5943 | | Herpes zoster<br>Patient must be immunocompromised; AND<br>The treatment must be administered within 72 hours of the onset of the rash. | Compliance with Authority Required procedures - Streamlined Authority Code 5943 |
| | C5947 | P5947 | | Recurrent moderate to severe oral or labial herpes<br>Episodic treatment<br>Patient must have HIV infection; AND<br>Patient must have a CD4 cell count of less than 500 million per litre.<br>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5947 |
| | C5948 | P5948 | | Recurrent moderate to severe oral or labial herpes<br>Suppressive therapy<br>Patient must have HIV infection; AND<br>Patient must have CD4 cell counts of less than 150 million per litre.<br>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid | Compliance with Authority Required procedures - Streamlined Authority Code 5948 |

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| | | | | amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | |
| | C5949 | P5949 | | Recurrent moderate to severe oral or labial herpes<br>Suppressive therapy<br>Patient must have HIV infection; AND<br>Patient must present with other opportunistic infections or AIDS defining tumours.<br>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5949 |
| | C5951 | P5951 | | Herpes zoster<br>The treatment must be administered within 72 hours of the onset of the rash. | Compliance with Authority Required procedures - Streamlined Authority Code 5951 |
| | C5954 | P5954 | | Recurrent moderate to severe genital herpes<br>Episodic treatment or suppressive therapy<br>Patient must be immunocompromised.<br>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5954 |
| | C5971 | P5971 | | Recurrent moderate to severe genital herpes<br>Suppressive therapy<br>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5971 |
| Faricimab | C13388 | P13388 | | Diabetic macular oedema (DMO)<br>Initial treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>Patient must have visual impairment due to diabetic macular oedema; AND<br>Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart | Compliance with Written Authority Required procedures |

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| | | | | administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>The treatment must be as monotherapy; OR<br>The treatment must be in combination with laser photocoagulation; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Authority approval for initial treatment of each eye must be sought.<br>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) A completed authority prescription form; and<br>(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).<br>All reports must be documented in the patient's medical records. | |
| | C13402 | P13402 | | Diabetic macular oedema (DMO)<br>Continuing treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND<br>The treatment must be as monotherapy; OR<br>The treatment must be in combination with laser photocoagulation; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13402 |
| | C13406 | P13406 | | Subfoveal choroidal neovascularisation (CNV)<br>Continuing treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must be due to age-related macular degeneration (AMD); AND | Compliance with Authority Required procedures - Streamlined Authority Code 13406 |

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| | | | | The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye. | |
| | C13424 | P13424 | | Subfoveal choroidal neovascularisation (CNV)<br>Initial treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must be due to age-related macular degeneration (AMD); AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Authority approval for initial treatment of each eye must be sought.<br>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) A completed authority prescription form; and<br>(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).<br>All reports must be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| | C13762 | P13762 | | Subfoveal choroidal neovascularisation (CNV)<br>Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must be due to age-related macular degeneration (AMD); AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2023; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Written Authority Required procedures |

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

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| | | | | latest version is located on the website specified in the Administrative Advice).<br>All reports must be documented in the patient's medical records. | |
| Febuxostat | C8921 | | | Chronic gout<br>The condition must be either chronic gouty arthritis or chronic tophaceous gout; AND<br>Patient must have a medical contraindication to allopurinol; OR<br>Patient must have a documented history of allopurinol hypersensitivity syndrome; OR<br>Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation. | Compliance with Authority Required procedures - Streamlined Authority Code 8921 |
| Fenofibrate | | P7640 | | For use in patients who are 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. | |
| Fentanyl | C5904 | P5904 | | Breakthrough pain<br>Continuing treatment<br>Patient must have cancer; AND<br>Patient must have pain directly attributable to cancer; AND<br>Patient must be assessed as receiving adequate management of their persistent pain with opioids; AND<br>Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR<br>The treatment must be used as short acting opioids are considered clinically inappropriate; OR<br>Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.<br>Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| | C5915 | P5915 | | Breakthrough pain<br>Initial treatment for dose titration<br>Patient must have cancer; AND<br>Patient must have pain directly attributable to cancer; AND<br>Patient must be assessed as receiving adequate management of their persistent pain with opioids; AND<br>Patient must have previously experienced inadequate pain relief following adequate doses of | Compliance with Authority Required procedures |

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| | | | | short acting opioids for the treatment of breakthrough pain; OR<br>The treatment must be used as short acting opioids are considered clinically inappropriate; OR<br>Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.<br>Patient must be undergoing palliative care. | |
| | C6026 | P6026 | | Breakthrough pain<br>Initial treatment for dose titration<br>Patient must have cancer; AND<br>Patient must have pain directly attributable to cancer; AND<br>Patient must be assessed as receiving adequate management of their persistent pain with opioids; AND<br>Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR<br>The treatment must be used as short acting opioids are considered clinically inappropriate; OR<br>Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.<br>Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| | C6027 | P6027 | | Breakthrough pain<br>Continuing treatment<br>Patient must have cancer; AND<br>Patient must have pain directly attributable to cancer; AND<br>Patient must be assessed as receiving adequate management of their persistent pain with opioids; AND<br>Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR<br>The treatment must be used as short acting opioids are considered clinically inappropriate; OR<br>Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.<br>Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| | C10745 | P10745 | | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than | Compliance with Authority Required |

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| | | | | 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must not be opioid naive; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | procedures - Streamlined Authority Code 10745 |
| | C10747 | P10747 | | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must not be opioid naive; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>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:<br>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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 | Compliance with Authority Required procedures - Streamlined Authority Code 10747 |

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| | | | | nurse practitioner in the past 12 months; or<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10751 | P10751 | | Chronic severe disabling pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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:<br>(i) is less than 12 months; or<br>(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the | Compliance with Authority Required procedures - Streamlined Authority Code 10751 |

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| | | | | Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C11696 | P11696 | | Severe disabling pain<br>Patient must not be opioid naive; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>Patient must be undergoing palliative care.<br>Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures |
| Ferrous fumarate | C6812 | | | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| Ferrous fumarate with folic acid | C6812 | | | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| Filgrastim | C6621 | | | Severe chronic neutropenia<br>Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR<br>Patient must have neutrophil dysfunction; AND<br>Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR<br>Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 6621 |
| | C6640 | | | Chronic cyclical neutropenia<br>Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 | Compliance with Authority Required |

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| | | | | days per cycle, measured over 3 separate cycles; AND<br>Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR<br>Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months. | procedures - Streamlined Authority Code 6640 |
| | C6653 | | | Mobilisation of peripheral blood progenitor cells<br>The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6653 |
| | C6654 | | | Mobilisation of peripheral blood progenitor cells<br>The treatment must be in a normal volunteer for use in allogeneic transplantation | Compliance with Authority Required procedures - Streamlined Authority Code 6654 |
| | C6655 | | | Assisting autologous peripheral blood progenitor cell transplantation<br>The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 6655 |
| | C6679 | | | Assisting bone marrow transplantation<br>Patient must be receiving marrow-ablative chemotherapy prior to the transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 6679 |
| | C6680 | | | Severe congenital neutropenia<br>Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; AND<br>Patient must have had a bone marrow examination that has shown evidence of maturational | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | arrest of the neutrophil lineage. | Code 6680 |
| | C7822 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must be at greater than 20% risk of developing febrile neutropenia; OR<br>Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 7822 |
| | C7843 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must have had a prior episode of febrile neutropenia; OR<br>Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 7843 |
| | C8667 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must have had a prior episode of febrile neutropenia; OR<br>Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 8667 |
| | C8668 | | | Mobilisation of peripheral blood progenitor cells<br>The treatment must be in a normal volunteer for use in allogeneic transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 8668 |
| | C8669 | | | Severe congenital neutropenia<br>Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; AND<br>Patient must have had a bone marrow examination that has shown evidence of maturational | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | arrest of the neutrophil lineage. | Code 8669 |
| | C8670 | | | Severe chronic neutropenia<br>Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR<br>Patient must have neutrophil dysfunction; AND<br>Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR<br>Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 8670 |
| | C8671 | | | Assisting bone marrow transplantation<br>Patient must be receiving marrow-ablative chemotherapy prior to the transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 8671 |
| | C8672 | | | Mobilisation of peripheral blood progenitor cells<br>The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 8672 |
| | C8673 | | | Chronic cyclical neutropenia<br>Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles; AND<br>Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR<br>Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 8673 |
| | C8674 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial | Compliance with Authority Required |

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| | | | | remission; AND<br>Patient must be at greater than 20% risk of developing febrile neutropenia; OR<br>Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | procedures - Streamlined Authority Code 8674 |
| | C8696 | | | Assisting autologous peripheral blood progenitor cell transplantation<br>The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 8696 |
| Finerenone | C14097 | | | Chronic kidney disease with Type 2 diabetes<br>Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND<br>Patient must not have known significant non-diabetic renal disease, prior to initiating treatment with this drug; AND<br>Patient must have an estimated glomerular filtration rate of 25 mL/min/1.73 m 2 or greater, prior to initiating treatment with this drug; AND<br>Patient must have a urinary albumin-to-creatinine ratio of 200 mg/g (22.6 mg/mmol) or greater, prior to initiating treatment with this drug; AND<br>Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND<br>Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug; AND<br>The treatment must be in combination with an SGLT2i unless medically contraindicated or intolerant; AND<br>Patient must not be receiving treatment with another selective nonsteroidal mineralocorticoid receptor antagonist, a renin inhibitor or a potassium-sparing diuretic; AND<br>Patient must not have established heart failure with reduced ejection fraction with an indication for treatment with a mineralocorticoid receptor antagonist. | Compliance with Authority Required procedures - Streamlined Authority Code 14097 |

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| Fingolimod | C10093 | | | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy.<br>Patient must weigh 40 kg or less. | Compliance with Authority Required procedures - Streamlined Authority Code 10093 |
| | C10162 | | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10162 |
| | C10172 | | | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 10172 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | |
| | C10198 | | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Patient must weigh 40 kg or less.<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10198 |
| Flecainide | C5550 | | | Serious ventricular cardiac arrhythmias<br>The treatment must be initiated in a hospital. | |
| | C5584 | | | Serious supra-ventricular cardiac arrhythmias | |
| Flucloxacillin | C5297 | | | Serious staphylococcal infection | |
| | C5298 | | | Serious staphylococcal infection | |
| | C5414 | P5414 | | Serious staphylococcal infection | |

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| | C6169 | P6169 | | Osteomyelitis | Compliance with Authority Required procedures - Streamlined Authority Code 6169 |
| Fluconazole | C5978 | | | Cryptococcal meningitis<br>The treatment must be maintenance therapy; AND<br>Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 5978 |
| | C5989 | | | Oesophageal candidiasis<br>Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 5989 |
| | C6002 | | | Cryptococcal meningitis | Compliance with Authority Required procedures - Streamlined Authority Code 6002 |
| | C6006 | | | Cryptococcal meningitis<br>Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6006 |
| | C6023 | | | Oropharyngeal candidiasis<br>Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 6023 |
| | C6030 | | | Oropharyngeal candidiasis<br>The treatment must be for prophylaxis; AND<br>Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 6030 |
| | C6031 | | | Oropharyngeal candidiasis<br>Patient must be immunosuppressed; AND<br>Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6031 |
| | C6032 | | | Oropharyngeal candidiasis<br>The treatment must be for prophylaxis; AND<br>Patient must be immunosuppressed; AND<br>Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6032 |
| | C6045 | | | Cryptococcal meningitis<br>The treatment must be maintenance therapy; AND<br>Patient must be immunosuppressed; AND<br>Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6045 |
| | C6046 | | | Oesophageal candidiasis<br>Patient must be immunosuppressed; AND<br>Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6046 |
| | C7898 | | | Fungal infection<br>The condition must be serious or life-threatening. | Compliance with Authority Required |

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| | | | | | procedures - Streamlined Authority Code 7898 |
| | C7934 | | | Fungal infection<br>The condition must be serious or life-threatening; AND<br>Patient must be unable to take a solid dose form of fluconazole | Compliance with Authority Required procedures - Streamlined Authority Code 7934 |
| Fluorouracil | C6266 | | | Patients requiring administration of fluorouracil by intravenous infusion | |
| | C6297 | | | Patients requiring administration of fluorouracil by intravenous injection | |
| Fluoxetine | C4755 | | | Major depressive disorders | |
| | C6277 | | | Obsessive-compulsive disorder | |
| Flutamide | C5816 | | | Metastatic (stage D) carcinoma of the prostate<br>The treatment must be in combination with GnRH (LH-RH) analogue therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5816 |
| Fluticasone furoate with umeclidinium and vilanterol | C12349 | | | Chronic obstructive pulmonary disease (COPD)<br>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<br>Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.<br>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 | Compliance with Authority Required procedures - Streamlined Authority Code 12349 |

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| | | | | interval/frequency that differs to that recommended in the approved Product Information. | |
| | C12603 | | | Severe asthma<br>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.<br>Patient must be at least 18 years of age.<br>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 12603 |
| Fluticasone furoate with vilanterol | C4711 | | | Asthma<br>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.<br>Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 4711 |
| | C4731 | | | Asthma<br>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.<br>Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 4731 |
| | C10121 | | | Chronic obstructive pulmonary disease (COPD)<br>Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy; AND<br>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 10121 |
| Fluticasone propionate | C14180 | | | Asthma<br>The treatment must not be a PBS benefit where this 50 microgram strength is being initiated in a patient over the age of 6.00 years. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 14180 |
| Fluticasone propionate with formoterol | C4395 | | | Asthma<br>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.<br>Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 4395 |
| Fluticasone propionate with salmeterol | C4930 | | | Asthma<br>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.<br>Patient must be aged 4 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4930 |
| | C10121 | | | Chronic obstructive pulmonary disease (COPD)<br>Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy; AND<br>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 10121 |
| Fluvastatin | | P7598 | | For use in patients who are 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. | |
| Fluvoxamine | C4755 | | | Major depressive disorders | |
| | C6277 | | | Obsessive-compulsive disorder | |
| Folic acid | C5820 | | | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| | C5824 | | | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| Folinic acid | C5938 | | | Megaloblastic anaemias<br>The condition must be a result of folic acid deficiency from the use of folic acid antagonists. | |

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| | C5973 | | | Megaloblastic anaemias<br>The condition must be a result of folic acid deficiency from the use of folic acid antagonists. | |
| Follitropin alfa | C5027 | | | Assisted Reproductive Technology<br>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5027 |
| | C6257 | | | Anovulatory infertility | |
| | C6321 | | | Infertility<br>The condition must be due to hypogonadotrophic hypogonadism; AND<br>The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis; AND<br>The treatment must be administered with human chorionic gonadotrophin. | |
| Follitropin alfa with lutropin alfa | C5250 | | | Stimulation of follicular development<br>Patient must have severe LH deficiency; AND<br>Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment; AND<br>Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5250 |
| Follitropin beta | C5027 | | | Assisted Reproductive Technology<br>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5027 |
| | C6257 | | | Anovulatory infertility | |
| | C6321 | | | Infertility<br>The condition must be due to hypogonadotrophic hypogonadism; AND | |

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| | | | | The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis; AND<br>The treatment must be administered with human chorionic gonadotrophin. | |
| Follitropin delta | C5027 | | | Assisted Reproductive Technology<br>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5027 |
| Fondaparinux | C5781 | | | Prevention of venous thromboembolism<br>Patient must be undergoing major hip surgery. | Compliance with Authority Required procedures - Streamlined Authority Code 5781 |
| | C5808 | | | Prevention of venous thromboembolism<br>Patient must be undergoing total knee replacement. | Compliance with Authority Required procedures - Streamlined Authority Code 5808 |
| Formoterol | C6355 | | | Asthma<br>Patient must experience frequent episodes of the condition; AND<br>Patient must be currently receiving treatment with oral corticosteroids; OR<br>Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids. | |
| Fosamprenavir | C4454 | | | HIV infection<br>Continuing<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| | C4512 | | | HIV infection | Compliance with |

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| | | | | Initial<br>Patient must be antiretroviral treatment naive; AND<br>The treatment must be in combination with other antiretroviral agents. | Authority Required procedures - Streamlined Authority Code 4512 |
| Fosaprepitant | C6852 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND<br>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND<br>Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.<br>No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.<br>Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle. | Compliance with Authority Required procedures - Streamlined Authority Code 6852 |
| | C6886 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND<br>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND<br>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.<br>No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6886 |
| | C6887 | | | Nausea and vomiting<br>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND<br>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND<br>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.<br>No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.<br>Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle. | Code 6887 |
| | C6891 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND<br>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND<br>Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.<br>No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6891 |
| Fosinopril with hydrochlorothiazide | C4389 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>The condition must be inadequately controlled with an ACE inhibitor; OR<br>The condition must be inadequately controlled with a thiazide diuretic. | |
| Fremanezumab | C12029 | P12029 | | Chronic migraine<br>Continuing treatment<br>Must be treated by a specialist neurologist or in consultation with a specialist neurologist; AND<br>Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 12029 |

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| | | | | Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month; AND<br>Patient must continue to be appropriately managed for medication overuse headache.<br>Patient must have the number of migraine days per month documented in their medical records. | |
| | C12064 | P12064 | | Chronic migraine<br>Initial treatment<br>Must be treated by a neurologist; AND<br>Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.<br>Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND<br>Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND<br>Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with this drug.<br>Patient must be aged 18 years or older.<br>Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.<br>Patient must have the number of migraine days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12064 |
| Fulvestrant | C11473 | | | Locally advanced or metastatic breast cancer<br>The condition must be hormone receptor positive; AND<br>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND<br>The condition must be inoperable.<br>Patient must not be premenopausal.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 11473 |
| Fusidic acid | C4963 | P4963 | | Serious staphylococcal infections<br>The treatment must be used in combination with another antibiotic; AND | |

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| | | | | The condition must be proven to be due to a staphylococcus. | |
| | C6133 | P6133 | | Osteomyelitis<br>The condition must be methicillin-resistant staphylococcal aureus (MRSA); AND<br>The treatment must be used in combination with other anti-staphylococcal antibiotics. | Compliance with Authority Required procedures - Streamlined Authority Code 6133 |
| Gabapentin | C4928 | | | Partial epileptic seizures<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 4928 |
| Galantamine | C10099 | | | Mild to moderately severe Alzheimer disease<br>Initial 2<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.<br>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.<br>Patients who qualify under this criterion are from 1 or more of the following groups:<br>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;<br>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;<br>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;<br>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome; | Compliance with Written Authority Required procedures |

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| | | | | (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;<br>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.<br>Application through this treatment restriction must be made in writing.<br>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.<br>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised. | |
| | C10100 | | | Mild to moderately severe Alzheimer disease<br>Initial 2<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.<br>Application through this treatment restriction must be made in writing.<br>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.<br>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised. | Compliance with Written Authority Required procedures |
| | C13938 | | | Mild to moderately severe Alzheimer disease<br>Continuing<br>Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND<br>Patient must demonstrate a clinically meaningful response to the initial treatment; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Prior to continuing treatment, a comprehensive assessment must be undertaken and | Compliance with Authority Required procedures - Streamlined Authority Code 13938 |

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| | | | | documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.<br>Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.<br>Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.<br>Clinically meaningful response to treatment is demonstrated in the following areas:<br>Patient's quality of life including but not limited to level of independence and happiness;<br>Patient's cognitive function including but not limited to memory, recognition and interest in environment;<br>Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour. | |
| | C13940 | | | Mild to moderately severe Alzheimer disease<br>Initial<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.<br>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.<br>Patients who qualify under this criterion are from 1 or more of the following groups:<br>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;<br>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;<br>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;<br>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome; | Compliance with Authority Required procedures |

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| | | | | (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;<br>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.<br>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | |
| | C13941 | | | Mild to moderately severe Alzheimer disease<br>Initial<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.<br>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | Compliance with Authority Required procedures |
| Galcanezumab | C12029 | P12029 | | Chronic migraine<br>Continuing treatment<br>Must be treated by a specialist neurologist or in consultation with a specialist neurologist; AND<br>Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month; AND<br>Patient must continue to be appropriately managed for medication overuse headache.<br>Patient must have the number of migraine days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12029 |
| | C12064 | P12064 | | Chronic migraine<br>Initial treatment | Compliance with Authority Required |

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| | | | | Must be treated by a neurologist; AND<br>Patient must not be undergoing concurrent treatment with the following PBS benefits: (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication.<br>Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND<br>Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND<br>Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with this drug.<br>Patient must be aged 18 years or older.<br>Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.<br>Patient must have the number of migraine days per month documented in their medical records. | procedures - Streamlined Authority Code 12064 |
| Ganciclovir | C4972 | | | Cytomegalovirus disease<br>Prophylaxis<br>Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 4972 |
| | C4999 | | | Cytomegalovirus disease<br>Prophylaxis<br>Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 4999 |
| | C5000 | | | Cytomegalovirus retinitis<br>Patient must be severely immunocompromised, including due to HIV infection. | Compliance with Authority Required procedures - Streamlined Authority |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | | Code 5000 |
| | C9404 | | | Cytomegalovirus disease<br>Prophylaxis<br>Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9404 |
| | C9526 | | | Cytomegalovirus disease<br>Prophylaxis<br>Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9526 |
| Ganirelix | C5046 | | | Assisted Reproductive Technology<br>The treatment must be for prevention of premature luteinisation and ovulation; AND<br>Patient must be undergoing controlled ovarian stimulation; AND<br>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5046 |
| Gefitinib | C4473 | | | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment<br>The treatment must be as monotherapy; AND<br>The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND<br>Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR<br>Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal; AND<br>Patient must have a WHO performance status of 2 or less.<br>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. | Compliance with Authority Required procedures |

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| | C7447 | | | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing treatment<br>The treatment must be as monotherapy; AND<br>Patient must have received an initial authority prescription for this drug for this condition; AND<br>Patient must not have progressive disease. | Compliance with Authority Required procedures - Streamlined Authority Code 7447 |
| Gemfibrozil | | P7640 | | For use in patients who are 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. | |
| Gemtuzumab ozogamicin | C12559 | | | Acute Myeloid Leukaemia<br>Induction treatment<br>Patient must have confirmed CD33-positive AML prior to initiation of treatment; AND<br>The condition must be de novo; AND<br>The condition must be previously untreated at the time of initiation (except for prior essential treatment with hydroxyurea or leukapheresis for patients with hyperleukocytic AML); AND<br>Patient must have confirmed intermediate/favourable cytogenetic risk; OR<br>Patient must have unknown cytogenetic risk due to inconclusive test results; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND<br>The condition must not be acute promyelocytic leukaemia; AND<br>The treatment must be in combination with standard intensive remission induction chemotherapy for this condition, which must include cytarabine and an anthracycline; AND<br>The treatment must not be used in combination with a tyrosine kinase inhibitor; AND<br>The condition must not be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive; AND<br>Patient must not receive more than 1 induction cycle under this restriction in a lifetime.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures |
| | C12566 | | | Acute Myeloid Leukaemia<br>Consolidation treatment<br>Patient must have achieved a complete remission following induction treatment with this drug for this condition; AND | Compliance with Authority Required procedures |

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| | | | | The treatment must be in combination with standard intensive remission consolidation chemotherapy for this condition, which must include cytarabine and an anthracycline; AND<br>Patient must not receive more than 2 consolidation cycles under this restriction in a lifetime.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>Complete remission following induction is defined as fewer than 5% blasts in a normocellular marrow and an absolute neutrophil count of more than 1.0 x $10^9$ cells/L with a platelet count of 100 x $10^9$ /L or more in the peripheral blood in the absence of transfusion.<br>Progressive disease is defined as the presence of any of the following:<br>a) Leukaemic cells in the CSF;<br>b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;<br>c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;<br>d) Extramedullary leukaemia. | |
| Gentamicin | C5451 | | | Perioperative use in ophthalmic surgery | |
| | C5476 | | | Perioperative use in ophthalmic surgery | |
| | C5477 | | | Suspected Pseudomonal eye infection | |
| | C5483 | | | Invasive ocular infection | |
| | C5499 | | | Suspected Pseudomonal eye infection | |
| Gilteritinib | C13166 | P13166 | | Relapsed or refractory Acute Myeloid Leukaemia<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The condition must not be acute promyelocytic leukaemia; AND<br>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 | Compliance with Authority Required procedures |

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| | | | | 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.<br>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. | |
| | C13167 | P13167 | | Relapsed or refractory Acute Myeloid Leukaemia<br>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022; AND<br>Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition; AND<br>The condition must have relapsed or been refractory prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND<br>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<br>The condition must not be acute promyelocytic leukaemia; AND<br>Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated.<br>Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.<br>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.<br>Progressive disease is defined as the presence of any of the following:<br>(a) Leukaemic cells in the CSF; or<br>(b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or<br>(c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or | Compliance with Authority Required procedures |

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| | | | | (d) Extramedullary leukaemia.<br>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. | |
| | C13242 | P13242 | | Relapsed or refractory Acute Myeloid Leukaemia<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>Patient must not be undergoing or have undergone a stem cell transplant.<br>Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.<br>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.<br>Progressive disease is defined as the presence of any of the following:<br>(a) Leukaemic cells in the CSF; or<br>(b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or<br>(c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or<br>(d) Extramedullary leukaemia. | Compliance with Authority Required procedures |
| Glatiramer | C6860 | | | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6860 |

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| | C7695 | | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7695 |
| Glecaprevir with pibrentasvir | C7593 | P7593 | | Chronic hepatitis C infection<br>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND<br>Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND<br>The treatment must be limited to a maximum duration of 8 weeks. | Compliance with Authority Required procedures |
| | C7615 | P7615 | | Chronic hepatitis C infection<br>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND<br>Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND<br>The treatment must be limited to a maximum duration of 12 weeks. | Compliance with Authority Required procedures |
| | C10268 | P10268 | | Chronic hepatitis C infection<br>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND | Compliance with Authority Required procedures |

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| | | | | Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND<br>The treatment must be limited to a maximum duration of 16 weeks.<br>The application must include details of the prior treatment regimen containing an NS5A inhibitor. | |
| Glucose and ketone indicator-urine | C5852 | | | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| Glucose indicator-urine | C5852 | | | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| Glycine with carbohydrate | C4704 | | | Isovaleric acidaemia | |
| Glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine | C5533 | | | Tyrosinaemia | |
| Glycomacropeptide and essential amino acids with vitamins and minerals | C4295 | | | Phenylketonuria | |
| | C5012 | | | Phenylketonuria | |
| | C5533 | | | Tyrosinaemia | |
| Glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine | C4295 | | | Phenylketonuria | |
| | C5012 | | | Phenylketonuria | |

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| Glycopyrronium | C4516 | | | Chronic obstructive pulmonary disease (COPD) | |
| Golimumab | C8641 | P8641 | | Severe active rheumatoid arthritis<br>Continuing treatment<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as:<br>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;<br>AND either of the following:<br>(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<br>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form(s); and<br>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form. | Compliance with Written Authority Required procedures |

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| | | | | It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.<br>Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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.<br>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. | |
| | C8642 | P8642 | | Severe active rheumatoid arthritis<br>Continuing Treatment - balance of supply<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| | C8713 | P8713 | | Severe active rheumatoid arthritis<br>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.<br>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<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 | Compliance with Authority Required procedures |

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| | | | | (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | |
| | C9063 | P9063 | | Severe psoriatic arthritis<br>Continuing treatment - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
| | C9064 | P9064 | | Severe psoriatic arthritis<br>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<br>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<br>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<br>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<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |

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| | C9069 | P9069 | | Severe psoriatic arthritis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR<br>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND<br>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>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).<br>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>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.<br>Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form(s); and<br>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information | Compliance with Written Authority Required procedures |

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| | | | | Form.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| | C9105 | P9105 | | Severe psoriatic arthritis<br>Continuing treatment<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as:<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein | Compliance with Written Authority Required procedures |

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| | | | | (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following:<br>(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<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form(s); and<br>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.<br>Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the | |

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| | | | | 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. | |
| | C9153 | P9153 | | Severe psoriatic arthritis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as:<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following:<br>(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<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form(s); and<br>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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. | |
| | C9155 | P9155 | | Severe psoriatic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND<br>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR | Compliance with Written Authority Required procedures |

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| | | | | Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.<br>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and<br>either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list of major joints:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form(s); and<br>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| | C9414 | P9414 | | Ankylosing spondylitis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Department of Human Services no later than 4 weeks from the date of completion of treatment.<br>This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:<br>(a) an ESR measurement no greater than 25 mm per hour; or<br>(b) a CRP measurement no greater than 10 mg per L; or<br>(c) an ESR or CRP measurement reduced by at least 20% from baseline.<br>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.<br>All measurements provided must be no more than 1 month old at the time of application.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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. | |
| | C9428 | P9428 | | Ankylosing spondylitis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND<br>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; or (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 | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND<br>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<br>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<br>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<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and<br>(ii) a completed BASDAI Assessment Form.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not | |

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| | | | | considered as a treatment failure. | |
| | C9429 | P9429 | | Ankylosing spondylitis<br>Initial treatment - 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<br>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<br>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<br>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<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
| | C9430 | P9430 | | Ankylosing spondylitis<br>Continuing treatment<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form. | Compliance with Written Authority Required procedures |

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| | | | | An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:<br>(a) an ESR measurement no greater than 25 mm per hour; or<br>(b) a CRP measurement no greater than 10 mg per L; or<br>(c) an ESR or CRP measurement reduced by at least 20% from baseline.<br>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.<br>All measurements provided must be no more than 1 month old at the time of application.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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. | |
| | C9431 | P9431 | | Ankylosing spondylitis<br>Continuing treatment - balance of supply<br>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |

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| | C9503 | P9503 | | Ankylosing spondylitis<br>Initial treatment - Initial 1 (new patient)<br>The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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; or (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); or (iii) limitation of chest expansion relative to normal values for age and gender; AND<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The application must include details of the NSAIDs trialled, their doses and duration of treatment.<br>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.<br>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.<br>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.<br>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:<br>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND<br>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C- | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | reactive protein (CRP) level greater than 10 mg per L.<br>The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.<br>Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. 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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and<br>(ii) a completed BASDAI Assessment Form; and<br>(iii) a completed Exercise Program Self Certification Form included in the supporting information form.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| | C9651 | P9651 | | Moderate to severe ulcerative colitis<br>Continuing treatment - balance of supply<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction. | |
| | C9705 | P9705 | | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>Patient must have a Mayo clinic score greater than or equal to 6; OR<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).<br>Patient must be aged 18 years or older.<br>Application for authorisation must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment. | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.<br>A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>Details of the accepted toxicities including severity can be found on the Department of Human Services website. | |

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| | C9745 | P9745 | | Moderate to severe ulcerative colitis<br>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<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR<br>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 14 weeks of treatment (weeks 0, 2, 6 and 10); OR<br>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 14 weeks of treatment (weeks 0, 2, 6 and 10); AND<br>The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment. | Compliance with Authority Required procedures |
| | C9770 | P9770 | | Moderate to severe ulcerative colitis<br>Continuing treatment<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.<br>Patient must be aged 18 years or older. | Compliance with Authority Required procedures |

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| | | | | Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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. | |
| | C9822 | P9822 | | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND<br>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 | Compliance with Written Authority Required procedures |

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| | | | | mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR<br>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR<br>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND<br>Patient must have a Mayo clinic score greater than or equal to 6; OR<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).<br>Patient must be aged 18 years or older.<br>Application for authorisation of initial treatment must be in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and<br>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.<br>A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.<br>A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10. | |

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| | | | | If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>Details of the accepted toxicities including severity can be found on the Department of Human Services website. | |
| | C9823 | P9823 | | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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.<br>Patient must be aged 18 years or older.<br>Application for authorisation must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following: | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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.<br>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. | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | C10434 | P10434 | | Non-radiographic axial spondyloarthritis<br>Continuing treatment - balance of supply<br>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| | C10436 | P10436 | | Non-radiographic axial spondyloarthritis<br>Initial 1 (New patient), Initial 2 (Change or re-commencement 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<br>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<br>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<br>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<br>The treatment must provide no more than the balance of up to 16 weeks treatment.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| | C10461 | P10461 | | Non-radiographic axial spondyloarthritis<br>Continuing treatment<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND<br>The treatment must not exceed a maximum of 24 weeks with this drug per authorised course | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.<br>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:<br>(a) a CRP measurement no greater than 10 mg per L; or<br>(b) a CRP measurement reduced by at least 20% from baseline.<br>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.<br>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. | |
| | C10515 | P10515 | | Non-radiographic axial spondyloarthritis<br>Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND<br>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<br>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<br>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND<br>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of | Compliance with Authority Required procedures |

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| | | | | Spondyloarthritis International Society (ASAS) criteria; AND<br>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND<br>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<br>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND<br>The treatment must not exceed a maximum of 16 weeks duration under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.<br>The following must be provided at the time of application and documented in the patient's medical records:<br>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and<br>(b) C-reactive protein (CRP) level greater than 10 mg per L.<br>The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.<br>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.<br>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. | |
| | C11431 | P11431 | | Non-radiographic axial spondyloarthritis<br>Initial treatment - Initial 1 (New patient)<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved | Compliance with Written Authority Required procedures |

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| | | | | by exercise but not rest; AND<br>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<br>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<br>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND<br>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND<br>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND<br>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<br>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND<br>The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.<br>The application must include details of the NSAIDs trialled, their doses and duration of treatment.<br>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.<br>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.<br>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.<br>The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application:<br>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 | |

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| | | | | scale; and<br>(b) C-reactive protein (CRP) level greater than 10 mg per L.<br>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.<br>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.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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).<br>The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | |
| | C11779 | P11779 | | Severe active rheumatoid arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | least 2 g daily; OR<br>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR<br>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction; AND<br>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.<br>Patient must be aged 18 years or older.<br>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.<br>The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.<br>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.<br>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 | |

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| | | | | intolerance including severity and dose for each DMARD must be provided in the authority application.<br>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either<br>(a) a total active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list of major joints:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>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 one month old at the time of initial application.<br>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.<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form(s); and<br>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.<br>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing | |

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| | | | | treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.<br>Where a response assessment is not provided within this 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.<br>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. | |
| | C11780 | P11780 | | Severe active rheumatoid arthritis<br>Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND<br>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND<br>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR<br>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND<br>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction; AND<br>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.<br>Patient must be aged 18 years or older. | Compliance with Written Authority Required procedures |

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| | | | | 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).<br>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.<br>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.<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form(s); and<br>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.<br>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.<br>Where a response assessment is not provided within this 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.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they | |

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| | | | | will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | |
| | C14171 | P14171 | | Severe active rheumatoid arthritis<br>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR<br>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<br>Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction; AND<br>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.<br>Patient must be aged 18 years or older.<br>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.<br>An adequate response to treatment is defined as:<br>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;<br>AND either of the following:<br>(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<br>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive | Compliance with Written Authority Required procedures |

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| | | | | movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.<br>Where a response assessment is not provided within this 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.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form(s); and<br>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.<br>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.<br>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. | |
| | C14190 | P14190 | | Non-radiographic axial spondyloarthritis<br>Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this | Compliance with Authority Required procedures |

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| | | | | condition in this treatment cycle; AND<br>The condition must not have responded inadequately to biological medicine on 4 occasions within the same treatment cycle; AND<br>The treatment must not exceed a maximum of 16 weeks with this drug under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.<br>Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS indication more than once in the current treatment cycle.<br>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.<br>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.<br>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:<br>(a) a CRP measurement no greater than 10 mg per L; or<br>(b) a CRP measurement reduced by at least 20% from baseline.<br>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.<br>BASDAI scores and CRP levels must be documented in the patient's medical records.<br>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.<br>The following must be provided at the time of application and documented in the patient's medical records:<br>(a) the BASDAI score; and<br>(b) the C-reactive protein (CRP) level. | |
| Goserelin | C4890 | | | Carcinoma of the prostate | |

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| | | | | The condition must be locally advanced (stage C); OR<br>The condition must be metastatic (stage D). | |
| | C4892 | | | Endometriosis<br>The condition must be visually proven; AND<br>The treatment must be for the short-term (up to 6 months). | |
| | C5437 | | | Breast cancer<br>The condition must be hormone receptor positive. | |
| | C7164 | | | Anticipated premature ovarian failure<br>Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure; AND<br>Patient must not receive more than 6 months' of treatment for this condition in a lifetime.<br>Patient must be pre-menopausal. | |
| Goserelin and bicalutamide | C4895 | | | Carcinoma of the prostate<br>The condition must be metastatic (stage D); AND<br>Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist. | |
| Granisetron | C4077 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.<br>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. | |
| | C4092 | | | Nausea and vomiting<br>The condition must be associated with radiotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 4092 |
| | C4118 | P4118 | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. | |
| | C4139 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.<br>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. | |
| | C10498 | P10498 | | Nausea and vomiting<br>The condition must be associated with radiotherapy being used to treat malignancy; OR<br>The condition must be associated with oral chemotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 10498 |
| Guanfacine | C8544 | | | Attention deficit hyperactivity disorder<br>Initial treatment<br>Must be treated by a paediatrician or psychiatrist.<br>The condition must be or have been diagnosed according to the DSM-5 criteria; AND<br>Patient must be receiving a maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) which has been stable for at least four weeks; AND<br>The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine); AND<br>Patient must be experiencing residual moderate to severe ADHD symptoms resulting in impaired functioning (social, academic or occupational), present in at least one setting (home, nursery/school/college/work, friends or family homes or other environment).<br>Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive. | Compliance with Authority Required procedures - Streamlined Authority Code 8544 |
| | C8585 | | | Attention deficit hyperactivity disorder<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine). | Compliance with Authority Required procedures - Streamlined Authority Code 8585 |

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| | C9031 | | | Attention deficit hyperactivity disorder<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR<br>Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR<br>Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR<br>Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously). | Compliance with Authority Required procedures - Streamlined Authority Code 9031 |
| | C9034 | | | Attention deficit hyperactivity disorder<br>Initial treatment<br>Must be treated by a paediatrician or psychiatrist.<br>The condition must be or have been diagnosed according to the DSM-5 criteria; AND<br>Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR<br>Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; OR<br>Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR<br>Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).<br>Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive. | Compliance with Authority Required procedures - Streamlined Authority Code 9034 |
| Guselkumab | C8877 | | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or | Compliance with Authority Required |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 20 weeks treatment; OR<br>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 20 weeks treatment; OR<br>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 20 weeks treatment; OR<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 20 weeks treatment; OR<br>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 20 weeks treatment; OR<br>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 20 weeks treatment; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.<br>Must be treated by a dermatologist. | procedures |
| | C9172 | | | Severe psoriatic arthritis<br>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<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>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<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 | Compliance with Authority Required procedures |

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| | | | | (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR<br>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<br>The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions. | |
| | C10742 | | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as:<br>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.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>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 | Compliance with Written Authority Required procedures |

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| | | | | those who meet the continuing restriction.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>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.<br>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. | |
| | C10743 | | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application. | Compliance with Written Authority Required procedures |

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| | | | | The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.<br>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.<br>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.<br>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. | |
| | C10806 | | | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as:<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and | Compliance with Written Authority Required procedures |

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| | | | | (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.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>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.<br>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.<br>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.<br>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. | |
| | C10807 | | | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply<br>Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR<br>Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.<br>Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| | C10889 | | | Severe chronic plaque psoriasis | Compliance with Written |

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| | | | | Continuing treatment, Face, hand, foot<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:<br>(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<br>(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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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.<br>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.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>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.<br>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 | Authority Required procedures |

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| | | | | treatment.<br>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.<br>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. | |
| | C10901 | | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the | Compliance with Written Authority Required procedures |

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| | | | | 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.<br>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.<br>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. | |
| | C11097 | | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Face, hand, foot (new patient)<br>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<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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 5 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; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>Where treatment with methotrexate, ciclosporin, apremilast 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. | Compliance with Written Authority Required procedures |

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| | | | | Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast 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.<br>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, 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.<br>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:<br>(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:<br>(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<br>(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;<br>(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.<br>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].<br>To demonstrate a response to treatment the application must be accompanied with the | |

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| | | | | 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.<br>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.<br>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. | |
| | C11114 | | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body (new patient)<br>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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 5 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; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>Where treatment with methotrexate, ciclosporin, apremilast 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.<br>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast or | Compliance with Written Authority Required procedures |

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| | | | | 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.<br>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, 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.<br>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:<br>(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.<br>(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.<br>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(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<br>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].<br>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.<br>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. | |

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| | | | | 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. | |
| | C11130 | | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:<br>(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<br>(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.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>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 | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>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.<br>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. | |
| | C11890 | | | Severe psoriatic arthritis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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<br>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<br>Patient must not receive more than 20 weeks of treatment under this restriction. | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.<br>Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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. | |
| | C11917 | | | Severe psoriatic arthritis<br>Continuing treatment<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as:<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following:<br>(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<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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).<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy. Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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. | |
| | C11918 | | | Severe psoriatic arthritis<br>Continuing treatment - balance of supply<br>Must be treated by a rheumatologist; OR | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | |
| | C11919 | | | Severe psoriatic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND<br>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR<br>Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.<br>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and<br>either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list of major joints: | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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). | |
| | C11979 | | | Severe psoriatic arthritis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR<br>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND<br>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>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).<br>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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). | |
| Haloperidol | | P11683 | | For use in patients receiving palliative care | |
| High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate | C4253 | | | Ketogenic diet<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; OR<br>Patient must have a glucose transport protein defect; OR<br>Patient must have pyruvate dehydrogenase deficiency.<br>KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. | |
| | C4289 | | | Ketogenic diet<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; OR<br>Patient must have a glucose transport protein defect; OR<br>Patient must have pyruvate dehydrogenase deficiency.<br>KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. | |
| | C4709 | | | Ketogenic diet<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; OR<br>Patient must have a glucose transport protein defect; OR<br>Patient must have pyruvate dehydrogenase deficiency.<br>KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | physician and/or neurologist. | |
| | C11644 | | | Ketogenic diet<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; OR<br>Patient must have a glucose transport protein defect; OR<br>Patient must have pyruvate dehydrogenase deficiency.<br>Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist. | |
| | C12096 | | | Ketogenic diet<br>Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of: (i) a metabolic physician, (ii) a neurologist.<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; OR<br>Patient must have a glucose transport protein defect; OR<br>Patient must have pyruvate dehydrogenase deficiency. | |
| | C12459 | | | Ketogenic diet<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; OR<br>Patient must have a glucose transport protein defect; OR<br>Patient must have pyruvate dehydrogenase deficiency; AND<br>Patient must have severe intestinal malabsorption of whole protein ketogenic diet formula; AND<br>Patient must have unsuccessfully trialled at least one of the PBS-listed products with the indication of: 'Ketogenic diet'.<br>This product must only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. | Compliance with Authority Required procedures |
| Human menopausal gonadotrophin | C5027 | | | Assisted Reproductive Technology<br>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5027 |
| Hyaluronic acid | C4105 | | | Severe dry eye syndrome<br>Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | | procedures - Streamlined Authority Code 4105 |
| Hydrocortisone | C4872 | | | Ulcerative colitis | |
| | C4893 | | | Proctitis | |
| | C4899 | | | Corticosteroid-responsive dermatoses | |
| | C4934 | | | Corticosteroid-responsive dermatoses | |
| | | P6252 | | For use in a hospital | |
| Hydromorphone | C10758 | P10758 | | Severe pain<br>The treatment must be for short term therapy of acute severe pain; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. | |
| | C10764 | P10764 | | Severe pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:<br>(i) severe disabling pain associated with malignant neoplasia; or<br>(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or<br>(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<br>(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 | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10770 | P10770 | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>Authorities for increased maximum quantities and/or repeats must only be considered for:<br>(i) severe disabling pain associated with proven malignant neoplasia; or<br>(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<br>(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<br>(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 | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10777 | P10777 | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10859 | P10859 | | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | C11697 | P11697 | | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>Patient must be undergoing palliative care.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures - Streamlined Authority Code 11697 |
| Hydroxocobalamin | C5840 | | | Pernicious anaemia<br>Patient must identify as Aboriginal or Torres Strait Islander. | |
| | C5841 | | | Anaemias associated with vitamin B12 deficiency<br>Patient must have had a gastrectomy; AND<br>The treatment must be for prophylaxis.<br>Patient must identify as Aboriginal or Torres Strait Islander. | |
| | C5854 | | | Proven vitamin B12 deficiencies other than pernicious anaemia<br>Patient must identify as Aboriginal or Torres Strait Islander. | |
| Hyoscine | C6207 | | | For use in patients receiving palliative care | Compliance with Authority Required procedures - Streamlined Authority Code 6207 |
| Hypromellose | C6073 | P6073 | | Severe dry eye syndrome, including Sjogren's syndrome | |
| | C6098 | P6098 | | Severe dry eye syndrome, including Sjogren's syndrome<br>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 | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | the Arrangements. | |
| | C6120 | | | Severe dry eye syndrome, including Sjogren's syndrome | |
| | C6172 | | | Severe dry eye syndrome<br>Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 6172 |
| Hypromellose with carbomer 980 | C6073 | P6073 | | Severe dry eye syndrome, including Sjogren's syndrome | |
| | C6098 | P6098 | | Severe dry eye syndrome, including Sjogren's syndrome<br>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. | |
| | C6120 | | | Severe dry eye syndrome, including Sjogren's syndrome | |
| Hypromellose with dextran | C6073 | P6073 | | Severe dry eye syndrome, including Sjogren's syndrome | |
| | C6098 | P6098 | | Severe dry eye syndrome, including Sjogren's syndrome<br>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. | |
| | C6120 | | | Severe dry eye syndrome, including Sjogren's syndrome | |
| | C6172 | | | Severe dry eye syndrome<br>Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 6172 |
| Ibandronic acid | C4922 | | | Bone metastases | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The condition must be due to breast cancer. | |
| | C5291 | | | Bone metastases<br>The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 5291 |
| | C9333 | | | Bone metastases<br>The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 9333 |
| Ibrutinib | C7858 | P7858 | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| | C12472 | P12472 | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have received treatment with another Bruton's tyrosine kinase (BTK) inhibitor for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease); OR<br>Patient must have developed intolerance to another Bruton's tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL; AND | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be considered unsuitable for treatment or retreatment with a purine analogue.<br>A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:<br>a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;<br>b) Age is 70 years or older;<br>c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;<br>d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;<br>e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test. | |
| | C12495 | P12495 | | Mantle cell lymphoma<br>Initial treatment<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy; OR<br>Patient must have developed intolerance to another Bruton's tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication. | Compliance with Authority Required procedures |
| | C12500 | P12500 | | Mantle cell lymphoma<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | condition. | |
| Ibuprofen | | P6149 | | Severe pain<br>Patient must be receiving palliative care. | |
| | | P6214 | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| | | P6256 | | Bone pain<br>The condition must be due to malignant disease. | |
| | | P6282 | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| | | P6283 | | Bone pain<br>The condition must be due to malignant disease. | |
| Icatibant | C7273 | | | Anticipated emergency treatment of an acute attack of hereditary angioedema<br>Initial<br>Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency; AND<br>Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema; AND<br>The condition must be assessed by a clinical immunologist; OR<br>The condition must be assessed by a respiratory physician; OR<br>The condition must be assessed by a specialist allergist; OR<br>The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.<br>The name of the specialist consulted must be provided at the time of application for initial supply.<br>The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.<br>Increased maximum quantities will be limited to 12 injections per authority prescription. | Compliance with Authority Required procedures |
| | C7274 | | | Anticipated emergency treatment of an acute attack of hereditary angioedema<br>Continuing<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required |

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| | | | | Increased maximum quantities will be limited to 12 injections per authority prescription. | procedures |
| Idarubicin | C6247 | | | Acute myelogenous leukaemia (AML) | |
| Idelalisib | C12479 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Initial treatment<br>The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; OR<br>The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition; AND<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>The condition must be CD20 positive; AND<br>Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); AND<br>Patient must be inappropriate for chemo-immunotherapy.<br>The prescriber must provide the CIRS score at the time of application.<br>A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:<br>1. Severe neutropenia defined as absolute neutrophil count of less than or equal to 1.0 x $10^9$/L; or<br>2. Severe thrombocytopenia defined as platelet count of less than or equal to 50 x $10^9$/L; or<br>3. Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test.<br>A pathology report confirming the patient is inappropriate for chemo-immunotherapy must be documented in the patient's medical records and must be no more than 4 weeks old at the time of application. | Compliance with Authority Required procedures |
| | C12480 | | | Refractory follicular B-cell non-Hodgkin's lymphoma<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Code 12480 |
| | C12490 | | | Refractory follicular B-cell non-Hodgkin's lymphoma<br>Initial treatment<br>The condition must be refractory to a prior therapy with rituximab within 6 months after completion of treatment with rituximab; AND<br>The condition must be refractory to a prior therapy with an alkylating agent within 6 months after completion of treatment with an alkylating agent; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.<br>The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.<br>The date of completion of prior therapies with rituximab and an alkylating agent must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| | C12491 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for Chronic lymphocytic leukaemia; OR<br>Patient must have previously received PBS-subsidised treatment with this drug for Small lymphocytic leukaemia; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |

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| Imatinib | C9203 | P9203 | | Acute lymphoblastic leukaemia<br>Initial treatment<br>Patient must be newly diagnosed; AND<br>The condition must be expressing the Philadelphia chromosome; OR<br>The condition must have the transcript BCR-ABL; AND<br>The treatment must be for induction and consolidation therapy; AND<br>The treatment must be in combination with chemotherapy or corticosteroids; AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised first line treatment with this drug for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition.<br>A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records. | Compliance with Authority Required procedures |

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| | C9204 | P9204 | | Aggressive systemic mastocytosis with eosinophilia<br>Initial treatment<br>Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene; AND<br>Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR<br>Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea); AND<br>The treatment must not exceed a maximum dose of 400 mg per day.<br>A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.<br>The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| | C9206 | P9206 | | Aggressive systemic mastocytosis with eosinophilia<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene; AND<br>Patient must have achieved and maintained a complete haematological response; AND<br>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed a maximum dose of 400 mg per day.<br>A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9206 |
| | C9207 | P9207 | | Acute lymphoblastic leukaemia<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; AND<br>The condition must be expressing the Philadelphia chromosome; OR<br>The condition must have the transcript BCR-ABL; AND<br>The treatment must be for maintenance of first complete remission; AND<br>The treatment must be in combination with chemotherapy or corticosteroids.<br>Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting. | Code 9207 |
| | C9209 | P9209 | | Dermatofibrosarcoma protuberans<br>Continuing treatment<br>The condition must be unresectable; OR<br>The condition must be locally recurrent; OR<br>The condition must be metastatic; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated a response to the PBS-subsidised treatment; AND<br>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed a maximum dose of 800 mg per day.<br>Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9209 |
| | C9238 | P9238 | | Gastrointestinal stromal tumour<br>Initial treatment<br>The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST); AND<br>Patient must be at high risk of recurrence following complete surgical resection of primary GIST; AND<br>The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining; AND<br>The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial | Compliance with Authority Required procedures |

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| | | | | plus continuing therapy).<br>High risk of recurrence is defined as:<br>Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or<br>Primary GIST greater than 10 cm with any mitotic rate; or<br>Primary GIST with a mitotic count of greater than 10/50 HPF.<br>A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.<br>The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records. | |
| | C9240 | P9240 | | Dermatofibrosarcoma protuberans<br>Initial treatment<br>The condition must be unresectable; OR<br>The condition must be locally recurrent; OR<br>The condition must be metastatic; AND<br>The treatment must not exceed a maximum dose of 800 mg per day.<br>Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| | C9243 | P9243 | | Myelodysplastic or myeloproliferative disorder<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The condition must be PDGFRB fusion gene-positive; AND<br>Patient must have achieved and maintained a complete haematological response; AND<br>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed a maximum dose of 400 mg per day.<br>A full blood examination report which demonstrates a complete haematological response and | Compliance with Authority Required procedures - Streamlined Authority Code 9243 |

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| | | | | evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records. | |
| | C9274 | P9274 | | Chronic eosinophilic leukaemia or Hypereosinophilic syndrome<br>Initial treatment<br>Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene; AND<br>The treatment must not exceed a maximum dose of 400 mg per day.<br>A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| | C9276 | P9276 | | Myelodysplastic or myeloproliferative disorder<br>Initial treatment<br>Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR<br>Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR<br>Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript; AND<br>Patient must have previously failed an adequate trial of conventional therapy with cytarabine; OR<br>Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR<br>Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea); AND<br>The treatment must not exceed a maximum dose of 400 mg per day.<br>A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records. | Compliance with Authority Required procedures |

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| | C9278 | P9278 | | Gastrointestinal stromal tumour<br>Continuing treatment<br>The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST); AND<br>Patient must be at high risk of recurrence following complete surgical resection of primary GIST; AND<br>The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy); AND<br>Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST. | Compliance with Authority Required procedures - Streamlined Authority Code 9278 |
| | C9296 | P9296 | | Chronic eosinophilic leukaemia or Hypereosinophilic syndrome<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have achieved and maintained a complete haematological response; AND<br>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed a maximum dose of 400 mg per day.<br>A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9296 |
| | C9319 | P9319 | | Malignant gastrointestinal stromal tumour<br>Initial Treatment<br>The condition must be metastatic; OR<br>The condition must be unresectable; AND<br>The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining; AND<br>The treatment must be commenced at a dose not exceeding 400 mg per day; AND<br>The treatment must not exceed 3 months under this restriction. | Compliance with Authority Required procedures |

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| | | | | Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.<br>Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.<br>A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)<br>A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.<br>Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.<br>Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records. | |
| | C12525 | P12525 | | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment<br>Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; AND<br>The condition must be in the blast phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR). | Compliance with Authority Required procedures - Streamlined Authority Code 12525 |
| | C12527 | P12527 | | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy | Compliance with Authority Required |

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| | | | | The condition must be a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the accelerated phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Accelerated phase is defined by the presence of 1 or more of the following:<br>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>3. Peripheral basophils greater than or equal to 20%; or<br>4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.<br>The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records. | procedures |
| | C12536 | P12536 | | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - first-line therapy<br>The condition must be in the chronic phase; AND | Compliance with Authority Required procedures - |

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| | | | | Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Streamlined Authority Code 12536 |
| | C12541 | P12541 | | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy<br>The condition must be a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the chronic phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Applications under this restriction will be limited to provide patients with a maximum of 18 months | Compliance with Authority Required procedures |

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| | | | | of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.<br>Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.<br>The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records. | |
| | C12542 | P12542 | | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment<br>Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; AND<br>The condition must be in the accelerated phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR). | Compliance with Authority Required procedures - Streamlined Authority Code 12542 |
| | C12543 | P12543 | | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy<br>The condition must be a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the blast phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND | Compliance with Authority Required procedures |

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| | | | | Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Blast crisis is defined as either:<br>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>2. Extramedullary involvement other than spleen and liver.<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.<br>The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records. | |
| | C12685 | P12685 | | Malignant gastrointestinal stromal tumour<br>Initial treatment<br>The condition must be metastatic; OR<br>The condition must be unresectable; AND<br>The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining; AND<br>The condition must have not achieved a response with this drug at a dose of 400 mg per day; AND<br>The treatment must not exceed 3 months under this restriction.<br>Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.<br>Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.<br>A response to treatment is defined as a decrease from baseline in the sum of the products of the | Compliance with Authority Required procedures |

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| | | | | perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)<br>A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.<br>Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.<br>Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records. | |
| | C13132 | P13132 | | Malignant gastrointestinal stromal tumour<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be given at a dose not exceeding 600 mg per day.<br>Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib<br>Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.<br>A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.) | Compliance with Authority Required procedures - Streamlined Authority Code 13132 |
| Imiquimod | C4229 | | | Superficial basal cell carcinoma<br>The condition must be previously untreated; AND<br>The condition must be confirmed by biopsy; AND | Compliance with Authority Required procedures |

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| | | | | Patient must have normal immune function; AND<br>The condition must not be suitable for treatment with surgical excision; OR<br>The condition must not be suitable for treatment with cryotherapy; OR<br>The condition must not be suitable for treatment with curettage with diathermy; AND<br>Patient must require topical drug therapy.<br>The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application. | |
| IncobotulinumtoxinA | C5222 | | | Spasmodic torticollis<br>Patient must have spasmodic torticollis; AND<br>The treatment must be as monotherapy; OR<br>The treatment must be as adjunctive therapy to current standard care.<br>Must be treated by a neurologist; OR<br>Must be treated by a plastic surgeon; OR<br>Must be treated by a rehabilitation specialist.<br>Patient must be aged 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 5222 |
| | C5360 | | | Blepharospasm<br>Patient must have blepharospasm.<br>Patient must be aged 18 years or older.<br>Must be treated by a neurologist; OR<br>Must be treated by an ophthalmologist; OR<br>Must be treated by an otolaryngology head and neck surgeon; OR<br>Must be treated by a plastic surgeon. | Compliance with Authority Required procedures - Streamlined Authority Code 5360 |
| | C9547 | | | Moderate to severe spasticity of the upper limb following an acute event<br>The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more; AND<br>The treatment must only be used as second line therapy when standard management has failed; OR<br>The treatment must only be used as an adjunct to physical therapy; AND<br>The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND | Compliance with Authority Required procedures - Streamlined Authority Code 9547 |

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| | | | | The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter; AND<br>Patient must not have established severe contracture in the limb to be treated.<br>Patient must be aged 18 years or older.<br>Must be treated by a neurologist; OR<br>Must be treated by an orthopaedic surgeon; OR<br>Must be treated by a rehabilitation specialist; OR<br>Must be treated by a plastic surgeon; OR<br>Must be treated by a geriatrician.<br>Standard management includes physiotherapy and/or oral spasticity agents. | |
| Indacaterol | C6366 | | | Chronic obstructive pulmonary disease (COPD) | |
| Indacaterol with glycopyrronium | C7798 | | | Chronic obstructive pulmonary disease (COPD)<br>Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR<br>Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR<br>Patient must have been stabilised on a combination of a LAMA and a LABA. | Compliance with Authority Required procedures - Streamlined Authority Code 7798 |
| Indacaterol with glycopyrronium and mometasone | C12603 | | | Severe asthma<br>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.<br>Patient must be at least 18 years of age.<br>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 12603 |
| Indacaterol with mometasone | C11360 | | | Asthma<br>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 - |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be aged 12 years or over. | Streamlined Authority Code 11360 |
| Indometacin | C6149 | P6149 | | Severe pain<br>Patient must be receiving palliative care. | |
| | C6214 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| | C6256 | | | Bone pain<br>The condition must be due to malignant disease. | |
| | C6282 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| | C6283 | | | Bone pain<br>The condition must be due to malignant disease. | |
| Infliximab | C11826 | P11826 | | Moderate to severe ulcerative colitis<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR<br>Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | treatment with this drug; OR<br>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.<br>Patient must be aged 18 years or older.<br>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>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 within 4 weeks prior to completing their current course of treatment.<br>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.<br>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.<br>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. | |
| | C11828 | P11828 | | Severe active rheumatoid arthritis<br>Continuing treatment with subcutaneous form or switching from intravenous form to | Compliance with Written Authority Required |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | subcutaneous form<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.<br>Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; OR<br>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND<br>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as:<br>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;<br>AND either of the following:<br>(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<br>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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). | procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>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 within 4 weeks prior to completing their current course of treatment.<br>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.<br>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.<br>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.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. | |
| | C11910 | P11910 | | Severe Crohn disease<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR<br>Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction; AND | Compliance with Written Authority Required procedures |

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| | | | | Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>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<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form.<br>Patient must be aged 18 years or older.<br>Applications for authorisation must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or<br>(ii) the reports and dates of the pathology test 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; and<br>(iii) the date of clinical assessment.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted up to 12 weeks of therapy and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>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 within 4 weeks prior to completing their current course of treatment. | |

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| | | | | 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.<br>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.<br>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.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period. | |
| | C13039 | P13039 | | Complex refractory Fistulising Crohn disease<br>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made<br>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND<br>Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |

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| | | | | The PBS administrator will confirm that:<br>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;<br>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application. | |
| | C13040 | P13040 | | Severe psoriatic arthritis<br>Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR<br>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.<br>Patient must be at least 18 years of age.<br>Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'. | Compliance with Authority Required procedures |
| | C13043 | P13043 | | Severe psoriatic arthritis<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Written Authority Required procedures |

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| | | | | Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>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<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An adequate response to treatment is defined as:<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following:<br>(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<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. | |
| | C13045 | P13045 | | Moderate to severe ulcerative colitis<br>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made<br>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND<br>Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent | Compliance with Written Authority Required procedures |

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| | | | | PBS authority application is approved/in the process of being approved.<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The PBS administrator will confirm that:<br>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;<br>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application. | |
| | C13056 | P13056 | | Complex refractory Fistulising Crohn disease<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug.<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An adequate response is defined as:<br>(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or<br>(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. | Compliance with Written Authority Required procedures |

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| | | | | The most recent fistula assessment must be no more than 1 month old at the time of application. | |
| | C13058 | P13058 | | Severe chronic plaque psoriasis<br>Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription<br>Must be treated by a dermatologist; AND<br>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR<br>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.<br>Patient must be at least 18 years of age.<br>Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'. | Compliance with Authority Required procedures |
| | C13061 | P13061 | | Moderate to severe ulcerative colitis<br>Balance of supply for Initial treatment, Continuing treatment - subcutaneous form<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); OR<br>Patient must have received insufficient therapy with this drug for this condition under the | Compliance with Authority Required procedures |

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| | | | | continuing treatment with subcutaneous form restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.<br>Patient must be at least 18 years of age. | |
| | C13068 | P13068 | | Severe Crohn disease<br>Balance of supply for Initial treatment, Continuing treatment - subcutaneous form<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks initial treatment (intravenous and subcutaneous inclusive); OR<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.<br>Patient must be at least 18 years of age. | Compliance with Authority Required procedures |
| | C13069 | P13069 | | Severe active rheumatoid arthritis<br>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made<br>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND<br>Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved. | Compliance with Written Authority Required procedures |

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| | | | | Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The PBS administrator will confirm that:<br>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;<br>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application. | |
| | C13077 | P13077 | | Ankylosing spondylitis<br>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made<br>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND<br>Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The PBS administrator will confirm that:<br>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;<br>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application. | Compliance with Written Authority Required procedures |
| | C13078 | P13078 | | Severe chronic plaque psoriasis<br>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made | Compliance with Written Authority Required procedures |

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

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

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | C13094 | P13094 | | Complex refractory Fistulising Crohn disease<br>Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR<br>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions.<br>Patient must be at least 18 years of age.<br>Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'. | Compliance with Authority Required procedures |
| | C13095 | P13095 | | Ankylosing spondylitis<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>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<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be at least 18 years of age. | Compliance with Written Authority Required procedures |

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| | | | | Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:<br>(a) an ESR measurement no greater than 25 mm per hour; or<br>(b) a CRP measurement no greater than 10 mg per L; or<br>(c) an ESR or CRP measurement reduced by at least 20% from baseline.<br>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.<br>All measurements provided must be no more than 1 month old at the time of application. | |
| | C13096 | P13096 | | Ankylosing spondylitis<br>Balance of supply (including switching formulation) where the full duration of treatment available under a particular treatment phase was not requested in the preceding prescription<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis; AND<br>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application did not specify the full quantity of repeat prescriptions available under the relevant PBS listing, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, (iii) this Balance of Supply listing is not being accessed on consecutive occasions; OR<br>Patient must be undergoing continuing PBS-subsidised treatment with this benefit, irrespective of formulation, where each of the following is true: (i) the most recent authority application was for a different formulation of this benefit, (ii) this authority application does not extend the current treatment phase beyond that available under the listing of the most recent authority application, | Compliance with Authority Required procedures |

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| | | | | (iii) this Balance of Supply listing is not being accessed on consecutive occasions.<br>Patient must be at least 18 years of age.<br>Where there is a current, approved PBS prescription with valid repeat prescriptions specified (i.e. where the drug formulation is changing), mark the prescription that is intended for no further supply as 'Cancelled'. | |
| | C13097 | P13097 | | Severe psoriatic arthritis<br>Initial treatment with the subcutaneous form where a concurrent PBS authority application for the intravenously (IV) administered formulation is being made<br>Must be treated by a specialist prescriber who is the same prescriber completing the PBS authority application for the IV administered formulation of this drug/biological medicine; AND<br>Patient must be undergoing treatment with this benefit where: (i) there is a concurrent PBS authority application for the IV administered formulation submitted for approval, (ii) the concurrent PBS authority application is approved/in the process of being approved.<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The PBS administrator will confirm that:<br>(i) there is a concurrent authority application for the intravenous (IV) formulation of this benefit for the patient;<br>(ii) the concurrent authority application for the IV formulation is to be approved before approving this authority application. | Compliance with Written Authority Required procedures |
| | C13104 | P13104 | | Severe active rheumatoid arthritis<br>Balance of supply for Initial treatment, Continuing treatment - subcutaneous form<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.<br>Patient must have received insufficient therapy with this drug for this condition under the Initial treatment with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); OR | Compliance with Authority Required procedures |

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| | | | | Patient must have received insufficient therapy with this drug for this condition under the continuing treatment with subcutaneous form restriction to complete 24 weeks treatment; AND<br>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND<br>The treatment must provide no more than the balance of up to 22 weeks treatment available under the Initial treatment - subcutaneous form; OR<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing treatment - subcutaneous form.<br>Patient must be at least 18 years of age. | |
| Inotuzumab ozogamicin | C9470 | | | Acute lymphoblastic leukaemia<br>Induction treatment<br>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<br>Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND<br>Patient must not have received more than 1 line of salvage therapy; AND<br>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND<br>The condition must be CD22-positive; AND<br>The condition must have more than 5% blasts in bone marrow; AND<br>The treatment must not be more than 3 treatment cycles under this restriction in a lifetime.<br>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.<br>The authority application must be made in writing and must include:<br>(1) two completed authority prescription forms;<br>(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and<br>(3) evidence that the condition is CD22-positive; and<br>(4) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and<br>(5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.<br>The treatment must not exceed 0.8mg per $m^2$for the first dose of a treatment cycle (Day 1), and | Compliance with Written Authority Required procedures |

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| | | | | 0.5mg per $m^2$for subsequent doses (Days 8 and 15) within a treatment cycle.<br>Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime. | |
| | C9601 | | | Acute lymphoblastic leukaemia<br>Consolidation treatment<br>Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND<br>Patient must have achieved a complete remission; OR<br>Patient must have achieved a complete remission with partial haematological recovery; AND<br>The treatment must not be more than 5 treatment cycles under this restriction in a lifetime; AND<br>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.<br>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.<br>The treatment must not exceed 0.5mg per $m^2$for all doses within a treatment cycle<br>Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime. | Compliance with Authority Required procedures |
| Insulin detemir | C5174 | | | Type 1 diabetes | |
| Interferon beta-1b | C6860 | | | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6860 |
| | C7695 | | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, | Compliance with Authority Required procedures - Streamlined Authority Code 7695 |

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| | | | | believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | |
| Interferon gamma-1b | C6222 | | | Chronic granulomatous disease<br>Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6222 |
| | C9639 | | | Chronic granulomatous disease<br>Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents. | Compliance with Authority Required procedures - Streamlined Authority Code 9639 |
| Ipilimumab | C6562 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Induction treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have received prior treatment with ipilimumab; AND<br>The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.<br>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 6562 |
| | C6585 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Re-induction treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction); AND<br>The treatment 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 6585 |

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| | | | | An initial objective response to treatment is defined as either:<br>(i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most recent course of ipilimumab; or<br>(ii) a partial or complete response.<br>The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated. | |
| | C8555 | | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Induction treatment<br>The condition must not have previously been treated; AND<br>The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.<br>Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.<br>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 8555 |
| | C11391 | | | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing combination treatment (with nivolumab) of first-line drug therapy<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND<br>The treatment must be in combination with nivolumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11391 |
| | C11478 | | | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial combination treatment (with nivolumab) as first-line drug therapy<br>The condition must be squamous type non-small cell lung cancer (NSCLC); AND | Compliance with Authority Required procedures - |

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| | | | | Patient must not have previously been treated for this condition in the metastatic setting; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>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<br>The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND<br>The treatment must be in combination with nivolumab.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Streamlined Authority Code 11478 |
| | C11930 | | | Unresectable malignant mesothelioma<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be in combination with PBS-subsidised nivolumab for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must not exceed a maximum total of 24 months in a lifetime for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 11930 |
| | C13841 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Induction treatment<br>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<br>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND<br>The condition must not be ocular or uveal melanoma; AND<br>The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.<br>Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.<br>Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.<br>The patient's body weight must be documented in the patient's medical records at the time | Compliance with Authority Required procedures - Streamlined Authority Code 13841 |

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| | | | | treatment is initiated. | |
| Ipratropium | C6331 | | | Asthma<br>Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer. | |
| | C6341 | | | Chronic obstructive pulmonary disease (COPD)<br>Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer. | |
| Irbesartan with hydrochlorothiazide | C4374 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>The condition must be inadequately controlled with an angiotensin II antagonist; OR<br>The condition must be inadequately controlled with a thiazide diuretic. | |
| Iron polymaltose complex | | P4302 | CN4302 | Iron deficiency anaemia<br>Patient must be undergoing chronic haemodialysis. | Compliance with Authority Required procedures - Streamlined Authority Code 4302 |
| Iron sucrose | | P4302 | CN4302 | Iron deficiency anaemia<br>Patient must be undergoing chronic haemodialysis. | Compliance with Authority Required procedures - Streamlined Authority Code 4302 |
| Isoleucine with carbohydrate | C5571 | | | Maple syrup urine disease | |
| Isotretinoin | C5224 | | | Severe cystic acne<br>The condition must be unresponsive to other therapy. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 5224 |
| Itraconazole | C5988 | | | Disseminated pulmonary histoplasmosis infection<br>Treatment and maintenance therapy<br>Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS). | Compliance with Authority Required procedures - Streamlined Authority Code 5988 |
| | C6005 | | | Systemic sporotrichosis | Compliance with Authority Required procedures - Streamlined Authority Code 6005 |
| | C6016 | | | Oropharyngeal candidiasis<br>Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 6016 |
| | C6022 | | | Systemic aspergillosis | Compliance with Authority Required procedures - Streamlined Authority Code 6022 |
| | C6035 | | | Oesophageal candidiasis<br>Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 6035 |
| | C6037 | | | Chronic pulmonary histoplasmosis infection<br>Treatment and maintenance therapy | Compliance with Authority Required |

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| | | | | Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS). | procedures - Streamlined Authority Code 6037 |
| | C6057 | | | Systemic histoplasmosis | Compliance with Authority Required procedures - Streamlined Authority Code 6057 |
| Ivabradine | C4979 | | | Chronic heart failure<br>Patient must be symptomatic with NYHA classes II or III; AND<br>Patient must be in sinus rhythm; AND<br>Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; AND<br>Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated; AND<br>Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.<br>Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.<br>The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 4979 |
| Ivermectin | C4319 | P4319 | | Onchocerciasis | Compliance with Authority Required procedures - Streamlined Authority Code 4319 |
| | C4328 | P4328 | | Strongyloidiasis | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 4328 |
| | C4565 | P4565 | | Crusted (Norwegian) scabies<br>The condition must be established by clinical and/or parasitological examination; AND<br>Patient must be undergoing topical therapy for this condition; OR<br>Patient must have a contraindication to topical treatment.<br>Patient must weigh 15 kg or over; AND<br>Patient must be 5 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4565 |
| | C4566 | P4566 | | Human sarcoptic scabies<br>The condition must be established by clinical and/or parasitological examination; AND<br>Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR<br>Patient must have a contraindication to topical treatment.<br>Patient must weigh 15 kg or over; AND<br>Patient must be 5 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4566 |
| | C12604 | P12604 | | Human sarcoptic scabies<br>The condition must be established by clinical and/or parasitological examination.<br>Patient must identify as Aboriginal or Torres Strait Islander; AND<br>Patient must weigh 15 kg or over; AND<br>Patient must be 5 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 12604 |
| Ixekizumab | C6696 | P6696 | | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply<br>Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR<br>Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND<br>The treatment must be as systemic monotherapy (other than methotrexate). | Compliance with Authority Required procedures |

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| | | | | Must be treated by a dermatologist. | |
| | C8830 | P8830 | | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as:<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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.<br>The most recent PASI assessment must be no more than 1 month old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.<br>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.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition | Compliance with Written Authority Required procedures |

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| | | | | within this treatment cycle.<br>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. | |
| | C8892 | P8892 | | Severe chronic plaque psoriasis<br>Continuing treatment, Face, hand, foot<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:<br>(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<br>(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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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.<br>The most recent PASI assessment must be no more than 1 month old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. | Compliance with Written Authority Required procedures |

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| | | | | It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.<br>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.<br>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.<br>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. | |
| | C9172 | P9172 | | Severe psoriatic arthritis<br>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<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>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<br>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<br>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<br>The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| | C9429 | P9429 | | Ankylosing spondylitis | Compliance with |

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| | | | | Initial treatment - 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<br>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<br>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<br>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<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Authority Required procedures |
| | C9431 | P9431 | | Ankylosing spondylitis<br>Continuing treatment - balance of supply<br>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
| | C10997 | P10997 | | Ankylosing spondylitis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | drug for this condition during the current treatment cycle; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application Form.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>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:<br>(a) an ESR measurement no greater than 25 mm per hour; or<br>(b) a CRP measurement no greater than 10 mg per L; or<br>(c) an ESR or CRP measurement reduced by at least 20% from baseline.<br>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.<br>All measurements provided must be no more than 4 weeks old at the time of application.<br>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 | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | of treatment is not considered as a treatment failure.<br>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. | |
| | C11030 | P11030 | | Ankylosing spondylitis<br>Continuing treatment<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application Form.<br>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:<br>(a) an ESR measurement no greater than 25 mm per hour; or<br>(b) a CRP measurement no greater than 10 mg per L; or<br>(c) an ESR or CRP measurement reduced by at least 20% from baseline.<br>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.<br>All measurements provided must be no more than 4 weeks old at the time of application.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>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. | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>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. | |
| | C11054 | P11054 | | Ankylosing spondylitis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND<br>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; or (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); or (iii) limitation of chest expansion relative to normal values for age and gender; AND<br>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<br>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<br>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<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR | Compliance with Written Authority Required procedures |

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| | | | | Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:<br>(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and<br>(ii) a BASDAI score.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>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.<br>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. | |
| | C11061 | P11061 | | Ankylosing spondylitis<br>Initial treatment - Initial 1 (new patient)<br>The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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; or (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); or (iii) limitation of chest expansion relative to normal values for age and gender; AND<br>Patient must have failed to achieve an adequate response following treatment with at least 2 non- | Compliance with Written Authority Required procedures |

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| | | | | steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The application must include details of the NSAIDs trialled, their doses and duration of treatment.<br>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.<br>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.<br>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.<br>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:<br>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and<br>(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.<br>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.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:<br>(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and<br>(ii) a baseline BASDAI score; and | |

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| | | | | (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and<br>(iv) baseline ESR and/or CRP level<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>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.<br>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. | |
| | C11089 | P11089 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and | Compliance with Written Authority Required procedures |

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| | | | | (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.<br>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.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>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.<br>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. | |
| | C11096 | P11096 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist. | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | An adequate response to treatment is defined as:<br>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.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>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.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>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.<br>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. | |
| | C11107 | P11107 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or | Compliance with Authority Required |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR<br>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 16 weeks treatment; OR<br>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 16 weeks treatment; OR<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR<br>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 16 weeks treatment; OR<br>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 16 weeks treatment; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.<br>Must be treated by a dermatologist. | procedures |
| | C11113 | P11113 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body (new patient)<br>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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 5 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at | Compliance with Written Authority Required procedures |

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| | | | | 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; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>Where treatment with methotrexate, ciclosporin, apremilast 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.<br>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast 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.<br>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, 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.<br>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:<br>(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.<br>(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.<br>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(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<br>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date | |

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| | | | | of commencement and duration of therapy].<br>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.<br>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.<br>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. | |
| | C11122 | P11122 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Face, hand, foot (new patient)<br>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<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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 5 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; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>Where treatment with methotrexate, ciclosporin, apremilast or acitretin is contraindicated | Compliance with Written Authority Required procedures |

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| | | | | according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.<br>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast 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.<br>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, 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.<br>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:<br>(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:<br>(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<br>(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;<br>(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.<br>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].<br>To demonstrate a response to treatment the application must be accompanied with the | |

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| | | | | 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.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>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.<br>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. | |
| | C11138 | P11138 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:<br>(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 | Compliance with Written Authority Required procedures |

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| | | | | (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.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>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.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>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.<br>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. | |
| | C11154 | P11154 | | Severe chronic plaque psoriasis | Compliance with Written |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.<br>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.<br>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.<br>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. | Authority Required procedures |
| | C11834 | P11834 | | Severe psoriatic arthritis | Compliance with Written |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR<br>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND<br>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>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).<br>All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for | Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>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.<br>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.<br>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. | |
| | C11918 | P11918 | | Severe psoriatic arthritis<br>Continuing treatment - balance of supply<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| | C11958 | P11958 | | Severe psoriatic arthritis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | condition in this treatment cycle; AND<br>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<br>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<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as:<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following:<br>(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<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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).<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>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. | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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. | |
| | C11959 | P11959 | | Severe psoriatic arthritis<br>Continuing treatment<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as:<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following:<br>(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<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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). | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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).<br>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.<br>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.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>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. | |
| | C11981 | P11981 | | Severe psoriatic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND<br>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.<br>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and<br>either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list of major joints:<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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).<br>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.<br>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 | |

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| | | | | treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| Ketoconazole | C6434 | | | Fungal or yeast infection<br>Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 6434 |
| Ketoprofen | C6214 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| Lacosamide | C8770 | P8770 | | Intractable partial epileptic seizures<br>Initial treatment<br>Must be treated by a neurologist.<br>The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents. | Compliance with Authority Required procedures - Streamlined Authority Code 8770 |
| | C8813 | P8813 | | Intractable partial epileptic seizures<br>Initial treatment<br>Must be treated by a neurologist.<br>The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents; AND<br>The treatment must be for dose titration purposes. | Compliance with Authority Required procedures - Streamlined Authority Code 8813 |

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| | C8815 | P8815 | | Intractable partial epileptic seizures<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8815 |
| | C12092 | P12092 | | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures<br>Must be treated by a neurologist; OR<br>Must be treated by a paediatrician; AND<br>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.<br>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<br>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 12092 |
| | C12225 | P12225 | | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures<br>Dose titration at the start of therapy, during therapy or to gradually cease treatment<br>Must be treated by a neurologist; OR<br>Must be treated by a paediatrician.<br>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<br>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; AND<br>The treatment must be for dose titration purposes. | Compliance with Authority Required procedures - Streamlined Authority Code 12225 |
| Lamivudine | C4454 | | | HIV infection<br>Continuing<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 4454 |
| | C4512 | | | HIV infection<br>Initial<br>Patient must be antiretroviral treatment naive; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4512 |
| | C4993 | | | Chronic hepatitis B infection<br>Patient must not have cirrhosis; AND<br>Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR<br>Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; AND<br>Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy. | Compliance with Authority Required procedures - Streamlined Authority Code 4993 |
| | C5036 | | | Chronic hepatitis B infection<br>Patient must have cirrhosis; AND<br>Patient must have detectable HBV DNA.<br>Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5036 |
| Lamivudine with zidovudine | C4454 | | | HIV infection<br>Continuing<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| | C4512 | | | HIV infection<br>Initial<br>Patient must be antiretroviral treatment naive; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 4512 |
| Lamotrigine | C11081 | | | Epileptic seizures<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR<br>Patient must be a woman of schildbearing potential. | Compliance with Authority Required procedures - Streamlined Authority Code 11081 |
| Lanadelumab | C12435 | | | Chronic treatment of hereditary angioedema Types 1 or 2<br>Continuing preventative treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not be PBS-subsidised in combination with a C1-esterase inhibitor concentrate.<br>Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.<br>Patient must be aged 12 years or older.<br>Patients who have successfully transitioned to a lower dosing frequency should be reviewed every 6 months to ensure they continue to demonstrate a sustained response<br>For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes. | Compliance with Authority Required procedures |
| | C12464 | | | Chronic treatment of hereditary angioedema Types 1 or 2<br>Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis)<br>Patient must have experienced at least 12 treated acute attacks of hereditary angioedema within the 6 month period prior to commencing treatment with this drug; AND<br>Patient must not have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema at the time of application; AND<br>The treatment must not be used in combination with a C1-esterase inhibitor concentrate. | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a clinical immunologist or a specialist allergist.<br>Patient must be aged 12 years or older.<br>For the purposes of administering this restriction, acute attacks of hereditary angioedema are those of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate<br>The baseline measurement of the number of treated acute attacks of hereditary angioedema within the 6 months prior to initiating treatment must be provided at the time of submitting this application. | |
| | C12467 | | | Chronic treatment of hereditary angioedema Types 1 or 2<br>Initial 2: New patient (commencing from National Blood Authority-funded C1-INH)<br>Patient must have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema immediately prior to receiving lanadelumab; AND<br>The treatment must not be used in combination with a C1-esterase inhibitor concentrate.<br>Must be treated by a clinical immunologist or a specialist allergist.<br>Patient must be aged 12 years or older. | Compliance with Authority Required procedures |
| Lanreotide | C4575 | | | Functional carcinoid tumour<br>The condition must be causing intractable symptoms; AND<br>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND<br>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 4575 |
| | C7025 | | | Acromegaly<br>The condition must be active; AND<br>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND<br>The treatment must be after failure of other therapy including dopamine agonists; OR | Compliance with Authority Required procedures - Streamlined Authority |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR<br>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND<br>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND<br>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.<br>In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | Code 7025 |
| | C7509 | | | Functional carcinoid tumour<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The condition must be causing intractable symptoms; AND<br>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND<br>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 7509 |
| | C7532 | | | Acromegaly<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The condition must be active; AND<br>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND<br>The treatment must be after failure of other therapy including dopamine agonists; OR | Compliance with Authority Required procedures - Streamlined Authority Code 7532 |

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| | | | | The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR<br>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND<br>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND<br>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.<br>In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | |
| | C9260 | | | Functional carcinoid tumour<br>The condition must be causing intractable symptoms; AND<br>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND<br>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 9260 |
| | C9261 | | | Acromegaly<br>The condition must be active; AND<br>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND<br>The treatment must be after failure of other therapy including dopamine agonists; OR<br>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR<br>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND | Compliance with Authority Required procedures - Streamlined Authority Code 9261 |

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| | | | | The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND<br>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.<br>In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | |
| | C10061 | | | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.<br>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Compliance with Authority Required procedures - Streamlined Authority Code 10061 |
| | C10075 | | | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.<br>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Compliance with Authority Required procedures - Streamlined Authority Code 10075 |
| | C10077 | | | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.<br>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Code 10077 |
| Lansoprazole | C5444 | | | Gastro-oesophageal reflux disease | |
| | C5512 | | | Scleroderma oesophagus | |
| | C8774 | P8774 | | Gastro-oesophageal reflux disease<br>The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR<br>The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease. | Compliance with Authority Required procedures - Streamlined Authority Code 8774 |
| | C8775 | P8775 | | Peptic ulcer<br>Initial treatment<br>Patient must have tested negative for helicobacter pylori infection; OR<br>Patient must have failed treatment with helicobacter pylori eradication therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 8775 |
| | C8776 | P8776 | | Gastro-oesophageal reflux disease<br>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 8776 |
| | C8780 | P8780 | | Scleroderma oesophagus | Compliance with Authority Required procedures - Streamlined Authority Code 8780 |

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| | C11310 | P11310 | | Complex gastro-oesophageal reflux disease (GORD)<br>One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control<br>Must be treated by a gastroenterologist; OR<br>Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR<br>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<br>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.<br>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<br>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<br>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<br>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<br>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.<br>Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction. | Compliance with Authority Required procedures |
| Lanthanum | C5491 | | | Hyperphosphataemia<br>Maintenance following initiation and stabilisation<br>The condition must not be adequately controlled by calcium; AND<br>Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND<br>The treatment must not be used in combination with any other non-calcium phosphate binding agents.<br>Patient must be undergoing dialysis for chronic kidney disease. | Code 5491 |
| | C5530 | | | Hyperphosphataemia<br>Initiation and stabilisation<br>The condition must not be adequately controlled by calcium; AND<br>Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR<br>The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND<br>The treatment must not be used in combination with any other non-calcium phosphate binding agents.<br>Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5530 |
| | C9762 | | | Hyperphosphataemia<br>Initiation and stabilisation<br>The condition must not be adequately controlled by calcium; AND<br>Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR<br>The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND<br>The treatment must not be used in combination with any other non-calcium phosphate binding agents.<br>Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9762 |
| Lapatinib | C9360 | | | Metastatic (Stage IV) HER2 positive breast cancer<br>Continuing treatment<br>Patient must have received an initial authority prescription for this drug for this condition; AND<br>The treatment must be in combination with capecitabine; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 9360 |

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| | | | | The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition; AND<br>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.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>The treatment must not exceed a lifetime total of one continuous course. | |
| | C13007 | | | Metastatic (Stage IV) HER2 positive breast cancer<br>Initial treatment<br>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<br>The treatment must be in combination with capecitabine; AND<br>Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR<br>Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR<br>Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; OR<br>Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; AND<br>The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition; AND<br>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.<br>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:<br>(i) details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and | Compliance with Written Authority Required procedures |

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| | | | | (ii) date of last treatment with a taxane and total number of cycles; or<br>(iii) dates of treatment with trastuzumab and pertuzumab; or<br>(iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab and pertuzumab; or<br>(v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab<br>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.<br>All reports must be documented in the patient's medical records.<br>Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.<br>If the application is submitted through HPOS upload or mail, it must include:<br>(a) a completed authority prescription form; and<br>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |
| Larotrectinib | C12980 | P12980 | | Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion<br>Continuing treatment<br>Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing.<br>The treatment must cease to be a PBS benefit upon radiographic progression; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.<br>Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'. | Compliance with Authority Required procedures |
| | C12981 | P12981 | | Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion<br>Initial treatment<br>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 | Compliance with Written Authority Required procedures |

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| | | | | 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<br>The condition must be a mammary analogue secretory carcinoma of the salivary gland confirmed through a pathology report from an Approved Pathology Authority (of any date); OR<br>The condition must be a secretory breast carcinoma confirmed through a pathology report from an Approved Pathology Authority (of any date); AND<br>The condition must be metastatic disease; OR<br>The condition must be both: (i) locally advanced, (ii) unresectable; OR<br>The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.<br>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.<br>Patient must be at least 18 years of age.<br>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:<br>(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.<br>(b) details of the pathology report establishing the carcinoma type (salivary gland/secretory breast carcinoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.<br>All reports must be documented in the patient's medical records.<br>If the application is submitted through HPOS upload or mail, it must include:<br>(a) a completed authority prescription form; and<br>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |
| | C12982 | P12982 | | Solid tumours (of any type) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion where treatment with this drug is/was initiated in a child<br>Initial treatment<br>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 | Compliance with Written Authority Required procedures |

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| | | | | 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<br>The condition must be metastatic disease; OR<br>The condition must be both: (i) locally advanced, (ii) unresectable; OR<br>The condition must be both: (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.<br>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.<br>Patient must be/have been under 18 years of age (i.e. prior to their 18 th birthday) at treatment initiation with this drug.<br>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:<br>(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.<br>All reports must be documented in the patient's medical records.<br>If the application is submitted through HPOS upload or mail, it must include:<br>(a) a completed authority prescription form; and<br>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |
| Latanoprost with timolol | C4343 | | | Elevated intra-ocular pressure<br>The condition must have been inadequately controlled with monotherapy; AND<br>Patient must have open-angle glaucoma; OR<br>Patient must have ocular hypertension. | |
| | C5038 | | | Elevated intra-ocular pressure<br>The condition must have been inadequately controlled with monotherapy; AND<br>Patient must have open-angle glaucoma; OR<br>Patient must have ocular hypertension. | |
| Leflunomide | C13753 | | | Severe active rheumatoid arthritis<br>Patient must have previously received, and failed to achieve an adequate response to, one or | |

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| | | | | more disease modifying anti-rheumatic drugs including methotrexate; OR<br>Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND<br>The treatment must be initiated by a physician. | |
| | C13771 | | | Severe active psoriatic arthritis<br>Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR<br>Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND<br>The treatment must be initiated by a physician. | |
| Lenvatinib | C6578 | P6578 | | Locally advanced or metastatic differentiated thyroid cancer<br>Continuing treatment<br>The condition must be refractory to radioactive iodine; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>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 6578 |
| | C6604 | P6604 | | Locally advanced or metastatic differentiated thyroid cancer<br>Initial treatment<br>The condition must be refractory to radioactive iodine; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have symptomatic progressive disease prior to treatment; OR<br>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<br>Patient must have thyroid stimulating hormone adequately repressed; AND<br>Patient must be one in whom surgery is inappropriate; AND<br>Patient must not be a candidate for radiotherapy with curative intent; AND<br>Patient must have a WHO performance status of 2 or less.<br>Radioactive iodine refractory is defined as:<br>a lesion without iodine uptake on a radioactive iodine (RAI) scan; or | Compliance with Authority Required procedures - Streamlined Authority Code 6604 |

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| | | | | having received a cumulative RAI dose of greater than or equal to 600 mCi; or<br>progression within 12 months of a single RAI treatment; or<br>progression after two RAI treatments administered within 12 months of each other. | |
| | C8584 | P8584 | | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not develop disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8584 |
| | C11168 | P11168 | | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not be suitable for transarterial chemoembolisation; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>Patient must have Child Pugh class A; AND<br>The condition must be untreated with systemic therapy; OR<br>Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following: (i) a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI), (ii) atezolizumab/bevacizumab combination therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 11168 |
| | C13921 | P13921 | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Initial treatment<br>Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND<br>The condition must be untreated; AND | Compliance with Authority Required procedures - Streamlined Authority Code 13921 |

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| | | | | Patient must have a WHO performance status of 2 or less.<br>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR<br>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records. | |
| | C13972 | P13972 | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR<br>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR<br>Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose.<br>In a patient who has experienced an intolerance to pembrolizumab, details of intolerance must be documented in the patient's medical record. | Compliance with Authority Required procedures - Streamlined Authority Code 13972 |
| | C14007 | P14007 | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements<br>Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 May 2023; AND<br>Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug and pembrolizumab of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented; AND<br>The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being | Compliance with Authority Required procedures - Streamlined Authority Code 14007 |

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| | | | | prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment. | |
| | C14041 | P14041 | | Advanced, metastatic or recurrent endometrial carcinoma<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.<br>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR<br>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; OR<br>Patient must be undergoing monotherapy with this drug after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose. | Compliance with Authority Required procedures - Streamlined Authority Code 14041 |
| | C14042 | P14042 | | Advanced, metastatic or recurrent endometrial carcinoma<br>Initial treatment<br>Patient must have received prior treatment with platinum-based chemotherapy; AND<br>The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.<br>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR<br>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14042 |

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| | C14043 | P14043 | | Advanced, metastatic or recurrent endometrial carcinoma<br>Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements<br>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND<br>The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (c) as monotherapy after completing an equivalent of 24 cumulative months of pembrolizumab treatment, measured from the first administered dose, (v) disease progression has not occurred whilst on treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 14043 |
| Lercanidipine with enalapril | C4398 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>The condition must be inadequately controlled with an ACE inhibitor; OR<br>The condition must be inadequately controlled with a dihydropyridine calcium channel blocker. | |
| Letrozole | C5464 | | | Breast cancer<br>The condition must be hormone receptor positive. | |
| Leuprorelin | C6409 | | | Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate | |
| | C12351 | | | Central precocious puberty<br>Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy<br>Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR<br>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND | |

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| | | | | Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication. | |
| | C13624 | | | Central precocious puberty<br>Initial treatment<br>Must be treated by a paediatric endocrinologist; OR<br>Must be treated by an endocrinologist specialising in paediatrics.<br>Patient must be of an age that is prior to their 10$^{th}$birthday if female; OR<br>Patient must be of an age that is prior to their 11$^{th}$birthday if male; AND<br>Patient must have had onset of signs/symptoms of central precocious puberty prior to their 8$^{th}$birthday if female; OR<br>Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9$^{th}$birthday if male. | |
| Leuprorelin and bicalutamide | C4895 | | | Carcinoma of the prostate<br>The condition must be metastatic (stage D); AND<br>Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist. | |
| Levetiracetam | C11077 | | | Partial epileptic seizures<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR<br>Patient must be a woman of childbearing potential; AND<br>Patient must be unable to take a solid dose form of levetiracetam; AND<br>The treatment must not be given concomitantly with brivaracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 11077 |
| | C11116 | | | Partial epileptic seizures<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR<br>Patient must be a woman of childbearing potential; AND<br>The treatment must not be given concomitantly with brivaracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 11116 |
| Levodopa with carbidopa | C5253 | | | Parkinson disease<br>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. | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | C10138 | P10138 | | Advanced Parkinson disease<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>The treatment must be commenced in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10138 |
| | C10161 | P10161 | | Advanced Parkinson disease<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>The treatment must be commenced in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10161 |
| | C10197 | P10197 | | Advanced Parkinson disease<br>Maintenance therapy<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>Patient must have been commenced on treatment in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10197 |
| | C10363 | P10363 | | Advanced Parkinson disease<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>The treatment must be commenced in a hospital-based movement disorder clinic; AND<br>Patient must require continuous administration of levodopa without an overnight break; OR<br>Patient must require a total daily dose of more than 2000 mg of levodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 10363 |
| | C10375 | P10375 | | Advanced Parkinson disease<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>The treatment must be commenced in a hospital-based movement disorder clinic; AND<br>Patient must require continuous administration of levodopa without an overnight break; OR<br>Patient must require a total daily dose of more than 2000 mg of levodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 10375 |
| | C10386 | P10386 | | Advanced Parkinson disease<br>Maintenance therapy | Compliance with Authority Required |

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| | | | | Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>Patient must have been commenced on treatment in a hospital-based movement disorder clinic; AND<br>Patient must require continuous administration of levodopa without an overnight break; OR<br>Patient must require a total daily dose of more than 2000 mg of levodopa. | procedures - Streamlined Authority Code 10386 |
| Levodopa with carbidopa and entacapone | C5212 | | | Parkinson disease<br>Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone. | |
| | C5288 | | | Parkinson disease<br>Patient must be being treated with levodopa decarboxylase inhibitor combinations; AND<br>Patient must be experiencing fluctuations in motor function due to end-of-dose effect. | |
| Levonorgestrel | C5135 | | | Idiopathic menorrhagia<br>The treatment must be in a patient where oral treatments are ineffective. | |
| | C5214 | | | Contraception | |
| | C5289 | | | Idiopathic menorrhagia<br>The treatment must be in a patient where oral treatments are contraindicated. | |
| Linagliptin | C6346 | | | Diabetes mellitus type 2<br>The treatment must be in combination with metformin; OR<br>The treatment must be in combination with a sulfonylurea; AND<br>Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR<br>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.<br>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose | Compliance with Authority Required procedures - Streamlined Authority Code 6346 |

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| | | | | co-transporter 2 (SGLT2) inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.<br>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | |
| | C6363 | | | Diabetes mellitus type 2<br>The treatment must be in combination with metformin; AND<br>The treatment must be in combination with a sulfonylurea; AND<br>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR<br>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.<br>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: | Compliance with Authority Required procedures - Streamlined Authority Code 6363 |

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| | | | | (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.<br>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | |
| | C6376 | | | Diabetes mellitus type 2<br>The treatment must be in combination with insulin; AND<br>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR<br>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.<br>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 | Compliance with Authority Required procedures - Streamlined Authority Code 6376 |

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| | | | | inhibitor, must be documented in the patient's medical records. | |
| | C7505 | | | Diabetes mellitus type 2<br>Continuing treatment<br>The treatment must be in combination with metformin; AND<br>The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND<br>Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7505 |
| | C7541 | | | Diabetes mellitus type 2<br>Initial treatment<br>The treatment must be in combination with metformin; AND<br>The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND<br>Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR<br>Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.<br>The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.<br>The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the | Compliance with Authority Required procedures - Streamlined Authority Code 7541 |

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| | | | | time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | |
| Linagliptin with metformin | C6333 | | | Diabetes mellitus type 2<br>Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR<br>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.<br>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.<br>A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6333 |
| | C6336 | | | Diabetes mellitus type 2<br>Continuing<br>Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 6336 |

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| | C6344 | | | Diabetes mellitus type 2<br>The treatment must be in combination with a sulfonylurea; AND<br>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR<br>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.<br>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.<br>A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6344 |
| | C6443 | | | Diabetes mellitus type 2<br>The treatment must be in combination with insulin; AND<br>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR | Compliance with Authority Required procedures - Streamlined Authority Code 6443 |

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| | | | | Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.<br>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | |
| | C7507 | | | Diabetes mellitus type 2<br>Initial treatment<br>The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND<br>Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR<br>Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.<br>The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 7507 |

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| | | | | The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | |
| | C7530 | | | Diabetes mellitus type 2<br>Continuing treatment<br>The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND<br>Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7530 |
| Liothyronine | C6382 | | | Thyroid cancer | Compliance with Authority Required procedures - Streamlined Authority Code 6382 |
| | C6410 | | | Hypothyroidism<br>The treatment must be for replacement therapy; AND<br>Patient must have documented intolerance to levothyroxine sodium; OR<br>Patient must have documented resistance to levothyroxine sodium. | Compliance with Authority Required procedures - Streamlined Authority Code 6410 |
| | C6475 | | | Hypothyroidism<br>The condition must be severe hypothyroidism; AND | Compliance with Authority Required procedures - |

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| | | | | The treatment must be for initiation of therapy only. | Streamlined Authority Code 6475 |
| Lipegfilgrastim | C7822 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must be at greater than 20% risk of developing febrile neutropenia; OR<br>Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 7822 |
| | C7843 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must have had a prior episode of febrile neutropenia; OR<br>Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 7843 |
| | C9224 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must be at greater than 20% risk of developing febrile neutropenia; OR<br>Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 9224 |
| | C9322 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must have had a prior episode of febrile neutropenia; OR<br>Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 9322 |
| Lisdexamfetamine | C10792 | | | Attention deficit hyperactivity disorder<br>Patient must require continuous coverage over 12 hours; AND<br>The treatment must not exceed a maximum daily dose of 70 mg with this drug. | Compliance with Authority Required procedures |

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| | | | | Patient must be aged between the ages of 6 and 18 years inclusive; OR<br>Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR<br>Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR<br>Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.<br>A retrospective diagnosis of ADHD for the purposes of administering this restriction is:<br>(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and<br>(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above. | |
| Loperamide | C6343 | P6343 | | Diarrhoea | Compliance with Authority Required procedures |
| | C6364 | P6364 | | Diarrhoea<br>Patient must identify as Aboriginal or Torres Strait Islander. | Compliance with Authority Required procedures - Streamlined Authority Code 6364 |
| Lopinavir with ritonavir | C4454 | | | HIV infection<br>Continuing<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| | C4512 | | | HIV infection<br>Initial<br>Patient must be antiretroviral treatment naive; AND | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | The treatment must be in combination with other antiretroviral agents. | Code 4512 |
| Lorlatinib | C13558 | | | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| | C13716 | | | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND<br>The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND<br>Patient must have a WHO performance status of 2 or less.<br>Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing. | Compliance with Authority Required procedures |
| Lurasidone | C4246 | | | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 4246 |
| Lutropin alfa | C5251 | | | Stimulation of follicular development<br>Patient must have severe LH deficiency; AND<br>Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5251 |

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| Macrogol 3350 | C4171 | P4171 | | Constipation<br>Patient must have malignant neoplasia. | |
| | C4173 | P4173 | | Chronic constipation<br>The condition must be inadequately controlled with first line interventions such as bulk-forming agents. | |
| | C4177 | P4177 | | Faecal impaction<br>The condition must be inadequately controlled with first line interventions such as bulk-forming agents. | |
| | C4179 | P4179 | | Constipation<br>Patient must be receiving palliative care. | |
| | C4180 | P4180 | | Constipation<br>Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function; AND<br>The condition must be unresponsive to other oral therapies. | |
| | C4576 | P4576 | | Constipation<br>Patient must have malignant neoplasia. | |
| | C4577 | P4577 | | Constipation<br>Patient must be receiving palliative care. | |
| | C4580 | P4580 | | Constipation<br>Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function; AND<br>The condition must be unresponsive to other oral therapies. | |
| | C4596 | P4596 | | Chronic constipation<br>The condition must be inadequately controlled with first line interventions such as bulk-forming agents. | |
| | C4601 | P4601 | | Faecal impaction | |

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| | | | | The condition must be inadequately controlled with first line interventions such as bulk-forming agents. | |
| | C6170 | P6170 | | Constipation<br>Patient must be receiving palliative care. | Compliance with Authority Required procedures - Streamlined Authority Code 6170 |
| | C6171 | P6171 | | Constipation<br>Patient must be receiving palliative care. | Compliance with Authority Required procedures - Streamlined Authority Code 6171 |
| Magnesium | C5466 | | | Chronic renal disease<br>Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 5466 |
| | C5506 | | | Hypomagnesaemia<br>Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 5506 |
| Mannitol | C7362 | | | Cystic fibrosis<br>The treatment must be as monotherapy; AND<br>Patient must be intolerant or inadequately responsive to dornase alfa.<br>Patient must be 6 years of age or older.<br>Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result. | <br>Compliance with Authority Required procedures - Streamlined Authority Code 7362 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.<br>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.<br>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.<br>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:<br>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND<br>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.<br>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | |
| | C7367 | | | Cystic fibrosis<br>The treatment must be in combination with dornase alfa; AND<br>Patient must be inadequately responsive to dornase alfa; AND<br>Patient must have trialled hypertonic saline for this condition.<br>Patient must be 6 years of age or older.<br>Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.<br>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.<br>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.<br>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.<br>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:<br>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND<br>(2) the patient or the patient's family (in the case of paediatric patients) and the treating | Compliance with Authority Required procedures - Streamlined Authority Code 7367 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | physician(s) must report a benefit in the clinical status of the patient.<br>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | |
| | C9527 | | | Cystic fibrosis<br>The treatment must be as monotherapy; AND<br>Patient must be intolerant or inadequately responsive to dornase alfa.<br>Patient must be 6 years of age or older.<br>Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.<br>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.<br>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.<br>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.<br>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:<br>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND<br>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.<br>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | Compliance with Authority Required procedures - Streamlined Authority Code 9527 |
| | C9593 | | | Cystic fibrosis<br>The treatment must be in combination with dornase alfa; AND<br>Patient must be inadequately responsive to dornase alfa; AND<br>Patient must have trialled hypertonic saline for this condition.<br>Patient must be 6 years of age or older.<br>Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved | Compliance with Authority Required procedures - Streamlined Authority Code 9593 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.<br>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.<br>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.<br>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.<br>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:<br>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND<br>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.<br>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | |
| Maraviroc | C5008 | | | HIV infection<br>Patient must be infected with CCR5-tropic HIV-1; AND<br>The treatment must be in addition to optimised background therapy; AND<br>The treatment must be in combination with other antiretroviral agents; AND<br>Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.<br>Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.<br>A tropism assay to determine CCR5 only strain status must be performed prior to initiation.<br>Individuals with CXCR4 tropism demonstrated at any time point are not eligible. | Compliance with Authority Required procedures - Streamlined Authority Code 5008 |
| Mecasermin | C13293 | | | Severe growth failure with primary insulin-like growth factor-1 deficiency<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; | Compliance with Written Authority Required procedures |

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| | | | | AND<br>Patient must have a bone age of less than 13.5 years (females); OR<br>Patient must have a bone age of less than 15.5 years (males); AND<br>The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing); AND<br>The condition must be responsive to this drug treatment as evidenced by each of: (i) patient is showing catch-up for height standard deviation score against Laron syndrome (growth hormone insensitivity syndrome) growth charts, (ii) patient has a growth velocity of greater than 2 cm per year (extrapolated for time on treatment) at the time of this continuing authority application; OR<br>The condition must be yet to respond to this drug treatment only for the reason of sub-optimal dosing.<br>Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; OR<br>Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician.<br>Patient must be aged from 2 years up until their 18 th birthday.<br>The continuing treatment authority application must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) The patient's height (cm);<br>(2) Where this authority application seeks to continue treatment where there has been an inadequate response to treatment due to sub-optimal dosing, state each of:<br>(i) the most recently prescribed dose (mg/kg) that resulted in an inadequate response;<br>(ii) the dose (mg/kg) (between 0.04 to 0.12) that was/will be subsequently prescribed to address the inadequate response;<br>(3) The patient's weight (kg);<br>(4) The patient's growth velocity in response to the preceding supply of drug (cm/year; extrapolated for time on treatment);<br>(5) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.<br>Height, growth velocity and weight measurements must not be more than three months old at the time of application.<br>Document growth improvements in the patient's medical records. | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | If the application is submitted through HPOS form upload or mail, it must include:<br>(i) A completed authority prescription form; and<br>(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). | |
| | C13317 | | | Severe growth failure with primary insulin-like growth factor-1 deficiency<br>Transitioning from non-PBS to PBS-subsidised supply - Grandfather patient<br>Patient must have commenced non-PBS-subsidised treatment with this drug prior to 1 October 2022; AND<br>The condition must be caused by severe primary insulin-like growth factor-1 deficiency (IGFD), with IGFD deficiency for the purpose of PBS subsidy defined as a basal IGF-1 level (measured any time prior to initiating treatment with this drug) below the 2.5 th percentile adjusted for each of: (i) age, (ii) gender; AND<br>The condition must have resulted in the patient experiencing short stature, with short stature for the purpose of PBS subsidy defined as the patient's height (measured any time prior to initiating treatment with this drug) being at least 3 standard deviations below the norm, adjusted for each of: (i) age, (ii) gender; AND<br>Patient must have had a growth velocity below the 25 th percentile for bone age plus sex measured over a 12 month interval (a 6 month interval for an older child) at the time the non-PBS-subsidised supply commenced; AND<br>The condition must not be caused by growth hormone deficiency; AND<br>Patient must have a bone age of less than 13.5 years (females); OR<br>Patient must have a bone age of less than 15.5 years (males); AND<br>The condition must not be caused by secondary causes of IGFD - prior to initiating treatment with this drug, the treating physician has at least excluded each of the following: (i) malnutrition, (ii) hypopituitarism, (iii) hypothyroidism, (iv) medication side effects; AND<br>The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing).<br>Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; OR<br>Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician; AND<br>Patient must be undergoing both: (i) continuing treatment with this drug, (ii) treatment that is yet | Compliance with Written Authority Required procedures |

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| | | | | to exceed 6 months of continuous treatment; OR<br>Patient must be undergoing each of: (i) continuing treatment with this drug, (ii) treatment that has exceeded 6 months duration, (iii) treatment that has resulted in both: (a) the patient showing catch-up for height standard deviation score against Laron syndrome (growth hormone insensitivity syndrome) growth charts, (b) a growth velocity of greater than 2 cm per year (extrapolated for time on treatment) at the time of this authority application; OR<br>Patient must be undergoing each of: (i) continuing treatment with this drug, (ii) treatment that has exceeded 6 months duration, (iii) treatment that is yet to establish the optimal dose.<br>Patient must be aged from 2 years up until their 18 th birthday.<br>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 the following:<br>(1) Date of commencing non-PBS-subsidised treatment:<br>State the month and year (mm/yy) that the first non-PBS-subsidised dose of this drug was administered.<br>(2) Insulin-like growth factor-1 deficiency:<br>State each of: (a) a basal IGF-1 level (ng/mL) measured prior to initiating non-PBS-subsidised treatment, (b) the measurement date (dd/mm/yy), (c) the name of the pathology result provider.<br>(3) Short stature:<br>State each of: (a) the patient's height (cm) at the time non-PBS-subsidised treatment was started, (b) the patient's current height (cm).<br>(4) Normal growth hormone levels:<br>State a growth hormone level measurement in mcg/L for this patient prior to having initiated non-PBS-subsidised treatment with this drug - this figure must be greater than 6.6 mcg/L.<br>(5) Bone age (where the patient had a chronological age of at least 2.5 years at the time of commencing non-PBS-subsidised treatment):<br>State each of: (a) the most recent bone age in numerical figures for this patient prior to initiating non-PBS-subsidised treatment with this drug, (b) the date (dd/mm/yy) of this determination that is within 12 months prior to initiating non-PBS-subsidised treatment with this drug;<br>(6) The patient's current growth velocity (cm/year) where there has been at least 6 months of non-PBS-subsidised treatment;<br>(7) The patient's current weight (kg);<br>(8) The prescribed dose (mg/kg) (between 0.04 to 0.12) that is sought for this authority application; | |

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| | | | | (9) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.<br>Current height, growth velocity and weight measurements must not be more than three months old at the time of application.<br>Document growth improvements in the patient's medical records.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(i) A completed authority prescription form; and<br>(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). | |
| | C13320 | | | Severe growth failure with primary insulin-like growth factor-1 deficiency<br>Initial treatment<br>The condition must be caused by severe primary insulin-like growth factor-1 deficiency (IGFD), with IGFD deficiency for the purpose of PBS subsidy defined as a basal IGF-1 level (measured any time prior to initiating treatment with this drug) below the 2.5 $^{th}$ percentile adjusted for each of: (i) age, (ii) gender; AND<br>The condition must have resulted in the patient experiencing short stature, with short stature for the purpose of PBS subsidy defined as the patient's height (measured any time prior to initiating treatment with this drug) being at least 3 standard deviations below the norm, adjusted for each of: (i) age, (ii) gender; AND<br>Patient must have a growth velocity below the 25 $^{th}$ percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); AND<br>The condition must not be caused by growth hormone deficiency; AND<br>Patient must have a bone age of less than 13.5 years (females); OR<br>Patient must have a bone age of less than 15.5 years (males); AND<br>The condition must not be caused by secondary causes of IGFD - prior to initiating treatment with this drug, the treating physician has at least excluded each of the following: (i) malnutrition, (ii) hypopituitarism, (iii) hypothyroidism, (iv) medication side effects; AND<br>The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing).<br>Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; OR | Compliance with Written Authority Required procedures |

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| | | | | Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician.<br>Patient must be aged from 2 years up until their 18 th birthday.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The initial treatment authority application must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include the following:<br>(1) Insulin-like growth factor-1 deficiency:<br>State each of: (a) the patient's most recent basal IGF-1 level measured (ng/mL), (b) the measurement date (dd/mm/yy), (c) the name of the pathology result provider;<br>(2) Short stature:<br>State the patient's height (cm);<br>(3) Normal growth hormone levels:<br>State the patient's most recent growth hormone level measurement (mcg/L) - this figure must be greater than 6.6 mcg/L;<br>(4) Bone age: (where the patient has a chronological age of at least 2.5 years):<br>State each of: (a) the patient's bone age in numerical figures at the time when it was most recently determined, (b) the date (dd/mm/yy) of this determination that is within 12 months of this authority application;<br>(5) The patient's weight (kg);<br>(6) The prescribed dose (mg/kg) (between 0.04 to 0.12);<br>(7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.<br>Height, growth velocity and weight measurements must not be more than three months old at the time of application.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(i) A completed authority prescription form; and<br>(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). | |
| Medroxyprogesterone | C5649 | | | Endometrial cancer | |

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| | C5731 | | | Advanced breast cancer<br>The condition must be hormone receptor positive. | |
| | C5791 | | | Breast cancer<br>The condition must be hormone receptor positive. | |
| | | P6244 | | Endometriosis | |
| Mefenamic acid | C6213 | | | Menorrhagia | |
| | C6229 | | | Dysmenorrhoea | |
| Meloxicam | C4907 | | | Rheumatoid arthritis<br>The treatment must be for symptomatic treatment. | |
| | C4962 | | | Osteoarthritis<br>The treatment must be for symptomatic treatment. | |
| Memantine | C10098 | | | Moderately severe Alzheimer disease<br>Initial 2<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.<br>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.<br>Patients who qualify under this criterion are from 1 or more of the following groups:<br>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;<br>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or | Compliance with Written Authority Required procedures |

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| | | | | innumerate;<br>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;<br>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;<br>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;<br>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.<br>Application through this treatment restriction must be made in writing.<br>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.<br>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised. | |
| | C10184 | | | Moderately severe Alzheimer disease<br>Initial 2<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.<br>Application through this treatment restriction must be made in writing.<br>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.<br>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised. | Compliance with Written Authority Required procedures |
| | C13936 | | | Moderately severe Alzheimer disease<br>Initial<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND | Compliance with Authority Required procedures |

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| | | | | The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.<br>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.<br>Patients who qualify under this criterion are from 1 or more of the following groups:<br>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;<br>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;<br>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;<br>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;<br>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;<br>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.<br>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | |
| | C13966 | | | Moderately severe Alzheimer disease<br>Continuing<br>Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND<br>Patient must demonstrate a clinically meaningful response to the initial treatment; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.<br>Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.<br>Re-assessments for a clinically meaningful response are to be undertaken and documented | Compliance with Authority Required procedures - Streamlined Authority Code 13966 |

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| | | | | every six months.<br>Clinically meaningful response to treatment is demonstrated in the following areas:<br>Patient's quality of life including but not limited to level of independence and happiness;<br>Patient's cognitive function including but not limited to memory, recognition and interest in environment;<br>Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour. | |
| | C14000 | | | Moderately severe Alzheimer disease<br>Initial<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.<br>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | Compliance with Authority Required procedures |
| Mesalazine | C4878 | | | Acute episode of mild to moderate ulcerative proctitis | |
| | C4888 | | | Acute episode of mild to moderate ulcerative colitis | Compliance with Authority Required procedures - Streamlined Authority Code 4888 |
| | C9443 | | | Crohn disease | |
| | C9444 | | | Ulcerative colitis | |
| Mesna | C5106 | | | Urothelial toxicity<br>Prophylaxis or reduction of toxicity<br>The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide. | |

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| | C5130 | | | Urothelial toxicity<br>Prophylaxis or reduction of toxicity<br>The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide. | |
| Methadone | C4902 | P4902 | | Chronic severe disabling pain<br>Initial treatment, for up to 3 months<br>Patient must be receiving palliative care; AND<br>The condition must be unresponsive to non-opioid analgesics. | Compliance with Authority Required procedures |
| | C4941 | P4941 | | Chronic severe disabling pain<br>Continuing treatment<br>Patient must be receiving palliative care; AND<br>The condition must be unresponsive to non-opioid analgesics. | Compliance with Authority Required procedures |
| | C10745 | P10745 | | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must not be opioid naive; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures - Streamlined Authority Code 10745 |

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| | C10747 | P10747 | | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must not be opioid naive; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>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:<br>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures - Streamlined Authority Code 10747 |
| | C10751 | P10751 | | Chronic severe disabling pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | 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:<br>(i) is less than 12 months; or<br>(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Code 10751 |
| | C11696 | P11696 | | Severe disabling pain<br>Patient must not be opioid naive; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>Patient must be undergoing palliative care.<br>Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures |

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| | C14178 | | | Opioid dependence<br>The treatment must be within a framework of medical, social and psychological treatment.<br>A medical practitioner must request a quantity (in millilitres) sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs. | Compliance with Authority Required procedures - Streamlined Authority Code 14178 |
| Methotrexate | | P5648 | | Patients requiring doses greater than 20 mg per week | |
| | | P6276 | | Patients receiving treatment with a high dose regimen | |
| | C7488 | | | Severe active rheumatoid arthritis<br>Patient must be unsuitable for administration of an oral form of methotrexate for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7488 |
| | C7518 | | | Severe psoriasis<br>The condition must not have adequately responded to topical treatment; AND<br>Patient must be unsuitable for administration of an oral form of methotrexate for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7518 |
| Methoxsalen | C10971 | P10971 | | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma<br>Initial treatment<br>Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR<br>Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR<br>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND | Compliance with Authority Required procedures - Streamlined Authority Code 10971 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.<br>Must be treated by a haematologist; OR<br>Must be treated by a medical physician working under the supervision of a haematologist.<br>Patient must be aged 18 years or over. | |
| | C10985 | P10985 | | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma<br>Initial treatment<br>Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR<br>Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR<br>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND<br>Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.<br>Must be treated by a haematologist; OR<br>Must be treated by a medical physician working under the supervision of a haematologist.<br>Patient must be aged 18 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 10985 |
| | C10988 | P10988 | | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma<br>Continuing treatment<br>Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND<br>Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS | Compliance with Authority Required procedures - Streamlined Authority Code 10988 |

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| | | | | indication; OR<br>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND<br>Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule.<br>Must be treated by a haematologist; OR<br>Must be treated by a medical physician working under the supervision of a haematologist.<br>A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment | |
| | C10989 | P10989 | | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma<br>Continuing treatment<br>Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND<br>Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR<br>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND<br>Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule.<br>Must be treated by a haematologist; OR<br>Must be treated by a medical physician working under the supervision of a haematologist.<br>A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment | Compliance with Authority Required procedures - Streamlined Authority Code 10989 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | C12531 | P12531 | | Chronic graft versus host disease<br>Continuing treatment<br>Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment; AND<br>Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode.<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition; AND<br>Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse. | Compliance with Authority Required procedures - Streamlined Authority Code 12531 |
| | C12546 | P12546 | | Chronic graft versus host disease<br>Initial treatment in a treatment episode<br>The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; OR<br>The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; OR<br>The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed.<br>Patient must be undergoing treatment with this drug that is being administered within at least one of: (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25$^{th}$dose) of a treatment episode; AND<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the | Compliance with Authority Required procedures - Streamlined Authority Code 12546 |

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| | | | | above mentioned specialist types; AND<br>Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation; AND<br>Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition. | |
| | C12567 | P12567 | | Chronic graft versus host disease<br>Continuing treatment<br>Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment; AND<br>Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode.<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition; AND<br>Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse. | Compliance with Authority Required procedures - Streamlined Authority Code 12567 |
| | C12579 | P12579 | | Chronic graft versus host disease<br>Initial treatment in a treatment episode<br>The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; OR<br>The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; OR<br>The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed. | Compliance with Authority Required procedures - Streamlined Authority Code 12579 |

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| | | | | Patient must be undergoing treatment with this drug that is being administered within at least one of: (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25th dose) of a treatment episode; AND<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation; AND<br>Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition. | |
| Methoxy polyethylene glycol-epoetin beta | C6294 | | | Anaemia associated with intrinsic renal disease<br>Patient must require transfusion; AND<br>Patient must have a haemoglobin level of less than 100 g per L; AND<br>Patient must have intrinsic renal disease, as assessed by a nephrologist. | Compliance with Authority Required procedures - Streamlined Authority Code 6294 |
| | C9688 | | | Anaemia associated with intrinsic renal disease<br>Patient must require transfusion; AND<br>Patient must have a haemoglobin level of less than 100 g per L; AND<br>Patient must have intrinsic renal disease, as assessed by a nephrologist. | Compliance with Authority Required procedures - Streamlined Authority Code 9688 |
| Methyldopa | C13887 | | | Hypertension<br>Patient must be pregnant. | Compliance with Authority Required procedures |
| Methylnaltrexone | C6180 | | | Opioid-induced constipation<br>The treatment must be in combination with oral laxatives; AND<br>Patient must be receiving palliative care; AND<br>Patient must have failed to respond to laxatives. | Compliance with Authority Required procedures - Streamlined Authority Code 6180 |

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| Methylphenidate | C6226 | | | Attention deficit hyperactivity disorder<br>Treatment must be in accordance with the law of the relevant State or Territory. | Compliance with Authority Required procedures |
| | C10717 | | | Attention deficit hyperactivity disorder<br>Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.<br>Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND<br>Patient must require continuous coverage over 12 hours; AND<br>The treatment must not exceed a maximum daily dose of 72 mg with this drug. | Compliance with Authority Required procedures |
| | C13922 | | | Attention deficit hyperactivity disorder<br>Patient must be aged between the ages of 6 and 18 years inclusive; OR<br>Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age; OR<br>Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age; OR<br>Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.<br>Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND<br>Patient must require continuous coverage over 8 hours; AND<br>The treatment must not exceed a maximum daily dose of 80 mg with this drug.<br>A retrospective diagnosis of ADHD for the purposes of administering this restriction is:<br>(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and<br>(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a: (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above. | Compliance with Authority Required procedures |
| Methylprednisolone | C4957 | P4957 | | Corticosteroid-responsive dermatoses | |
| | C6209 | | | Local intra-articular or peri-articular infiltration | |

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| | C6218 | P6218 | | Corticosteroid-responsive dermatoses<br>The condition must cover 40-60% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6218 |
| | C6231 | P6231 | | Corticosteroid-responsive dermatoses<br>The condition must cover >80% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6231 |
| | C6232 | P6232 | | Corticosteroid-responsive dermatoses<br>The condition must cover 10-20% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6232 |
| | C6246 | P6246 | | Corticosteroid-responsive dermatoses<br>The condition must cover 20-40% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6246 |
| | C6263 | P6263 | | Corticosteroid-responsive dermatoses<br>The condition must cover 60-80% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6263 |
| | C6273 | | | Local intra-articular or peri-articular infiltration | |
| | C6302 | P6302 | | Eczema | |

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| Metoclopramide | | P6084 | CN6084 | Nausea or gastric stasis<br>Patient must be receiving palliative care. | Compliance with Authority Required procedures - Streamlined Authority Code 6084 |
| | | P11683 | | For use in patients receiving palliative care | |
| Metoprolol succinate | C5324 | | | Moderate to severe heart failure<br>Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated. | |
| Metronidazole | C5701 | | | Anaerobic infections | |
| | C5702 | | | Anaerobic infections | |
| Mianserin | C6278 | | | Severe depression | |
| Miconazole | C6434 | | | Fungal or yeast infection<br>Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 6434 |
| Mifepristone and misoprostol | C14202 | | | Termination of an intra-uterine pregnancy<br>The condition must be an intra-uterine pregnancy of up to 63 days of gestation. | Compliance with Authority Required procedures - Streamlined Authority Code 14202 |
| Milk powder -- synthetic | C6208 | | | Hypercalcaemia<br>Patient must be under the age of 4 years. | |
| Milk protein and fat formula with vitamins | C6658 | | | Ketogenic diet<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; OR | |

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| and minerals -- carbohydrate free | | | | Patient must have a glucose transport protein defect; OR<br>Patient must have pyruvate dehydrogenase deficiency; OR<br>Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance. | |
| Minocycline | C5995 | | | Severe acne<br>The condition must not be responding to other tetracyclines. | |
| Minoxidil | C5177 | | | Severe refractory hypertension<br>The treatment must be initiated by a consultant physician. | |
| Mirtazapine | C5650 | | | Major depressive disorders | |
| Moclobemide | C5650 | | | Major depressive disorders | |
| Modafinil | C10935 | | | Narcolepsy<br>Initial 2 - treatment of narcolepsy with cataplexy<br>Must be treated by a qualified sleep medicine practitioner or neurologist.<br>The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR<br>The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal; AND<br>Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months; AND<br>Patient must have a definite history of cataplexy documented in their medical records for auditing purposes; AND<br>Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.<br>The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:<br>(a) a psychiatric disorder;<br>(b) a cardiovascular disorder;<br>(c) a history of substance abuse;<br>(d) glaucoma; | Compliance with Authority Required procedures |

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| | | | | (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information. | |
| | C10968 | | | Narcolepsy<br>Continuing or change of treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR<br>Patient must have previously received PBS-subsidised treatment with armodafinil for this condition. | Compliance with Authority Required procedures |
| | C10970 | | | Narcolepsy<br>Initial 1 - treatment of narcolepsy without cataplexy<br>Must be treated by a qualified sleep medicine practitioner or neurologist.<br>The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR<br>The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal; AND<br>Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months; AND<br>Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR<br>Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; AND<br>Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.<br>The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk:<br>(a) a psychiatric disorder;<br>(b) a cardiovascular disorder;<br>(c) a history of substance abuse;<br>(d) glaucoma;<br>(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information. | Compliance with Written Authority Required procedures |

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| | | | | The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.<br>The authority application must be made in writing and must include the following:<br>(a) a completed authority prescription form; and<br>(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and<br>(c) details of the contraindication or intolerance to dexamfetamine sulfate; and<br>(d) either:<br>(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or<br>(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.<br>The polysomnography, MSLT or EEG test reports must be provided with the authority application. | |
| Molnupiravir | C13748 | | | SARS-CoV-2 infection<br>Patient must have received a positive polymerase chain reaction (PCR) test result; OR<br>Patient must have received a positive rapid antigen test (RAT) result; AND<br>Patient must have at least one sign or symptom attributable to COVID-19; AND<br>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND<br>The treatment must be initiated within 5 days of symptom onset.<br>Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.<br>For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:<br>1. The patient is in residential aged care<br>2. The patient has disability with multiple comorbidities and/or frailty<br>3. Neurological conditions, including stroke and dementia and demyelinating conditions<br>4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease<br>5. Heart failure, coronary artery disease, cardiomyopathies<br>6. Obesity (BMI greater than 30 $kg/m^2$)<br>7. Diabetes type I or II, requiring medication for glycaemic control<br>8. Renal impairment (eGFR less than 60mL/min)<br>9. Cirrhosis | Compliance with Authority Required procedures - Streamlined Authority Code 13748 |

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| | | | | 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<br>11. Past COVID-19 infection episode resulting in hospitalisation.<br>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.<br>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.<br>Access to this drug through this restriction is permitted irrespective of vaccination status.<br>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.<br>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.<br>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | |
| | C13759 | | | SARS-CoV-2 infection<br>Patient must have received a positive polymerase chain reaction (PCR) test result; OR<br>Patient must have received a positive rapid antigen test (RAT) result; AND<br>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND<br>The treatment must be initiated within 5 days of symptom onset; OR<br>The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.<br>Patient must be at least 70 years of age.<br>Access to this drug through this restriction is permitted irrespective of vaccination status.<br>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.<br>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.<br>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | Compliance with Authority Required procedures - Streamlined Authority Code 13759 |

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| | C13765 | | | SARS-CoV-2 infection<br>Patient must have received a positive polymerase chain reaction (PCR) test result; OR<br>Patient must have received a positive rapid antigen test (RAT) result; AND<br>Patient must have at least one sign or symptom attributable to COVID-19; AND<br>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND<br>The treatment must be initiated within 5 days of symptom onset.<br>Patient must be both: (i) at least 50 years of age, (ii) at high risk.<br>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:<br>1. The patient is in residential aged care,<br>2. The patient has disability with multiple comorbidities and/or frailty,<br>3. Neurological conditions, including stroke and dementia and demyelinating conditions,<br>4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease,<br>5. Heart failure, coronary artery disease, cardiomyopathies,<br>6. Obesity (BMI greater than 30 kg/$m^2$),<br>7. Diabetes type I or II, requiring medication for glycaemic control,<br>8. Renal impairment (eGFR less than 60mL/min),<br>9. Cirrhosis, or<br>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.<br>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.<br>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.<br>Access to this drug through this restriction is permitted irrespective of vaccination status.<br>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.<br>Where a RAT is used to confirm diagnosis, available information about the test result, testing | Compliance with Authority Required procedures - Streamlined Authority Code 13765 |

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| | | | | date, location and test provider (where relevant) must be recorded on the patient record.<br>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | |
| | C13824 | | | SARS-CoV-2 infection<br>Patient must have received a positive polymerase chain reaction (PCR) test result; OR<br>Patient must have received a positive rapid antigen test (RAT) result; AND<br>Patient must have at least one sign or symptom attributable to COVID-19; AND<br>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND<br>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<br>The treatment must be initiated within 5 days of symptom onset.<br>Patient must be at least 18 years of age.<br>For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:<br>1. Any primary or acquired immunodeficiency including:<br>a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,<br>b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),<br>c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR<br>2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:<br>a. Chemotherapy or whole body radiotherapy,<br>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,<br>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),<br>d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least | Compliance with Authority Required procedures - Streamlined Authority Code 13824 |

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| | | | | 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR<br>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<br>4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR<br>5. People with disability with multiple comorbidities and/or frailty.<br>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records<br>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.<br>Access to this drug through this restriction is permitted irrespective of vaccination status.<br>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.<br>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.<br>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | |
| Mometasone | C4957 | P4957 | | Corticosteroid-responsive dermatoses | |
| | C6218 | P6218 | | Corticosteroid-responsive dermatoses<br>The condition must cover 40-60% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6218 |
| | C6231 | P6231 | | Corticosteroid-responsive dermatoses<br>The condition must cover >80% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 6231 |
| | C6232 | P6232 | | Corticosteroid-responsive dermatoses<br>The condition must cover 10-20% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6232 |
| | C6246 | P6246 | | Corticosteroid-responsive dermatoses<br>The condition must cover 20-40% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6246 |
| | C6263 | P6263 | | Corticosteroid-responsive dermatoses<br>The condition must cover 60-80% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6263 |
| Montelukast | C6666 | | | Asthma<br>First-line prevention<br>Patient must be aged 2 to 5 years inclusive.<br>The condition must be frequent intermittent; OR<br>The condition must be mild persistent; AND<br>The treatment must be the single preventer agent; AND<br>The treatment must be an alternative to sodium cromoglycate; OR<br>The treatment must be an alternative to nedocromil sodium. | Compliance with Authority Required procedures - Streamlined Authority Code 6666 |
| | C6674 | | | Asthma<br>First-line prevention<br>The condition must be frequent intermittent; OR<br>The condition must be mild persistent; AND<br>The treatment must be the single preventer agent; AND | Compliance with Authority Required procedures - Streamlined Authority Code 6674 |

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| | | | | The treatment must be an alternative to sodium cromoglycate; OR<br>The treatment must be an alternative to nedocromil sodium.<br>Patient must be aged 6 to 14 years inclusive. | |
| | C7781 | | | Asthma<br>Prevention of condition<br>The condition must be exercise-induced; AND<br>The treatment must be as an alternative to adding salmeterol xinafoate; OR<br>The treatment must be an alternative to adding formoterol fumarate; AND<br>The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid; AND<br>Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.<br>Patient must be aged 6 to 14 years inclusive. | Compliance with Authority Required procedures - Streamlined Authority Code 7781 |
| Morphine | C6168 | P6168 | | Severe disabling pain<br>Patient must be receiving palliative care; AND<br>The condition must be unresponsive to non-opioid analgesics. | Compliance with Authority Required procedures |
| | C9248 | P9248 | | Chronic Breathlessness<br>Patient must be receiving palliative care. | |
| | C10748 | P10748 | | Chronic severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>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:<br>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management | Compliance with Authority Required procedures - Streamlined Authority Code 10748 |

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| | | | | review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10752 | P10752 | | Chronic severe pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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:<br>(i) is less than 12 months; or<br>(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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. | Compliance with Authority Required procedures - Streamlined Authority Code 10752 |

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| | | | | Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10755 | P10755 | | Chronic severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures - Streamlined Authority Code 10755 |
| | C10756 | P10756 | | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR | Compliance with Authority Required procedures |

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| | | | | Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10762 | P10762 | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR<br>The treatment must be part of pre-operative care; OR<br>The treatment must be used as an analgesic adjunct in general anaesthesia.<br>Authorities for increased maximum quantities and/or repeats must only be considered for:<br>(i) severe disabling pain associated with proven malignant neoplasia; or<br>(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<br>(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<br>(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 | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | planned in the next 3 months.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10764 | P10764 | | Severe pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:<br>(i) severe disabling pain associated with malignant neoplasia; or<br>(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or<br>(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<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the | |

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| | | | | Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10765 | P10765 | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR<br>The treatment must be part of pre-operative care; OR<br>The treatment must be used as an analgesic adjunct in general anaesthesia.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10770 | P10770 | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>Authorities for increased maximum quantities and/or repeats must only be considered for:<br>(i) severe disabling pain associated with proven malignant neoplasia; or | |

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| | | | | (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<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10775 | P10775 | | Cancer pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have cancer pain; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>Authorities for increased maximum quantities and/or repeats must only be considered for:<br>(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<br>(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic | |

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| | | | | 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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10777 | P10777 | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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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| | C10814 | P10814 | | Chronic severe disabling pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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:<br>(i) is less than 12 months; or<br>(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures |
| | C10836 | P10836 | | Chronic severe disabling pain<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. | Compliance with Authority Required procedures |

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| | C10837 | P10837 | | Cancer pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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:<br>(i) is less than 12 months; or<br>(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10839 | | | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR<br>The treatment must be part of pre-operative care; OR<br>The treatment must be used as an analgesic adjunct in general anaesthesia. | |

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| | C10858 | P10858 | | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>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:<br>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures |
| | C10859 | | | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or | |

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| | | | | intolerance. | |
| | C10891 | P10891 | | Cancer pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have cancer pain; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C11697 | P11697 | | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>Patient must be undergoing palliative care.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures - Streamlined Authority Code 11697 |
| | C11753 | P11753 | | Severe disabling pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR | Compliance with Authority Required |

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| | | | | Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>Patient must be undergoing palliative care.<br>Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | procedures |
| Moxonidine | C4944 | | | Hypertension<br>Patient must be receiving concurrent antihypertensive therapy. | |
| Mupirocin | C6647 | | | Staphylococcus aureus infection<br>Patient must have nasal colonisation with the bacteria.<br>Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 6647 |
| Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain | C5540 | | | Primary and relapsing superficial urothelial carcinoma of the bladder | |
| | C5597 | | | Primary and relapsing superficial urothelial carcinoma of the bladder | |
| Mycobacterium bovis (Bacillus Calmette and Guerin), Tice strain | C5540 | | | Primary and relapsing superficial urothelial carcinoma of the bladder | |
| | C5597 | | | Primary and relapsing superficial urothelial carcinoma of the bladder | |
| Mycophenolic acid | | P4084 | CN4084 | Prophylaxis of renal allograft rejection<br>Management<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 4084 |
| | | P4095 | CN4095 | WHO Class III, IV or V lupus nephritis | Compliance with |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Management<br>The condition must be proven by biopsy.<br>Must be treated by a nephrologist or in consultation with a nephrologist.<br>The name of the consulting nephrologist must be included in the patient medical records. | Authority Required procedures - Streamlined Authority Code 4095 |
| | | P5554 | CN5554 | Management of cardiac allograft rejection<br>Management (initiation, stabilisation and review of therapy)<br>Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5554 |
| | | P5600 | CN5600 | Management of cardiac allograft rejection<br>Management (initiation, stabilisation and review of therapy)<br>Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5600 |
| | | P5653 | CN5653 | Management of renal allograft rejection<br>Management (initiation, stabilisation and review of therapy)<br>Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5653 |
| | | P5795 | CN5795 | Management of renal allograft rejection<br>Management (initiation, stabilisation and review of therapy)<br>Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5795 |
| | | P9689 | CN9689 | Management of renal allograft rejection<br>Management (initiation, stabilisation and review of therapy)<br>Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9689 |

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| | | P9690 | CN9690 | Management of cardiac allograft rejection<br>Management (initiation, stabilisation and review of therapy )<br>Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9690 |
| | | P9691 | CN9691 | Management of renal allograft rejection<br>Management (initiation, stabilisation and review of therapy)<br>Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9691 |
| | | P9692 | CN9692 | Prophylaxis of renal allograft rejection<br>Management<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9692 |
| | | P9693 | CN9693 | Management of cardiac allograft rejection<br>Management (initiation, stabilisation and review of therapy)<br>Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND<br>The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9693 |
| | | P9809 | CN9809 | WHO Class III, IV or V lupus nephritis<br>Management<br>The condition must be proven by biopsy.<br>Must be treated by a nephrologist or in consultation with a nephrologist.<br>The name of the consulting nephrologist must be included in the patient medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9809 |
| Nafarelin | C5046 | | | Assisted Reproductive Technology<br>The treatment must be for prevention of premature luteinisation and ovulation; AND<br>Patient must be undergoing controlled ovarian stimulation; AND<br>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | of the Medicare Benefits Schedule. | Code 5046 |
| | C6517 | | | Endometriosis<br>Subsequent treatment, for up to 6 months<br>The condition must be visually proven; AND<br>The treatment must not be within 2 years of the end of the previous course of treatment with this drug; AND<br>Patient must have had a recent bone density assessment.<br>The date of the bone density assessment must be recorded in the patient's medical records. | |
| | C6552 | | | Endometriosis<br>Initial treatment, for up to 6 months<br>The condition must be visually proven. | |
| Naltrexone | C13967 | | | Alcohol dependence<br>The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence/controlled consumption. | Compliance with Authority Required procedures - Streamlined Authority Code 13967 |
| Naproxen | C4124 | | | Bone pain<br>The condition must be due to malignant disease; AND<br>Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent. | Compliance with Authority Required procedures - Streamlined Authority Code 4124 |
| | C4159 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component; AND<br>Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent. | Compliance with Authority Required procedures - Streamlined Authority Code 4159 |
| | C6149 | | | Severe pain<br>Patient must be receiving palliative care. | |

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| | C6150 | | | Severe pain<br>Patient must be undergoing palliative care.<br>Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent. | |
| | C6196 | | | Severe pain<br>Patient must be receiving palliative care. | |
| | C6214 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| | C6256 | | | Bone pain<br>The condition must be due to malignant disease. | |
| | C6282 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| | C6283 | | | Bone pain<br>The condition must be due to malignant disease. | |
| | C6368 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| | C6387 | | | Bone pain<br>The condition must be due to malignant disease. | |
| | C6463 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |
| | C6471 | | | Bone pain<br>The condition must be due to malignant disease. | |
| Naratriptan | C4562 | | | Migraine attack<br>The condition must have usually failed to respond to analgesics in the past. | Compliance with Authority Required procedures |

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| | C5849 | | | Migraine attack<br>The condition must have usually failed to respond to analgesics in the past; AND<br>Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance. | Compliance with Authority Required procedures |
| | C5850 | | | Migraine attack<br>The condition must have usually failed to respond to analgesics in the past; AND<br>Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences. | Compliance with Authority Required procedures |
| | C5859 | | | Migraine attack<br>The condition must have usually failed to respond to analgesics in the past; AND<br>Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs. | Compliance with Authority Required procedures |
| | C5860 | | | Migraine attack<br>The condition must have usually failed to respond to analgesics in the past; AND<br>Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs. | Compliance with Authority Required procedures |
| | C5887 | | | Migraine attack<br>The condition must have usually failed to respond to analgesics in the past; AND<br>Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs. | Compliance with Authority Required procedures |
| Natalizumab | C13625 | | | Clinically definite relapsing-remitting multiple sclerosis<br>Must be treated by a neurologist.<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support); AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR | Compliance with Authority Required procedures - Streamlined Authority Code 13625 |

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| | | | | Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.<br>The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.<br>Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.<br>For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug. | |
| | C13718 | | | Clinically definite relapsing-remitting multiple sclerosis<br>Must be treated by a neurologist.<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support); AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR<br>Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.<br>The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.<br>Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.<br>For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 13718 |
| Nebivolol | C5324 | | | Moderate to severe heart failure | |

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| | | | | Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated. | |
| Netupitant with Palonosetron | C5991 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND<br>The treatment must be in combination with dexamethasone; AND<br>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.<br>No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5991 |
| | C5994 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND<br>The treatment must be in combination with dexamethasone; AND<br>Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.<br>No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5994 |
| | C6879 | | | Nausea and vomiting<br>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND<br>The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle; AND<br>Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.<br>No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6879 |
| | C6937 | | | Nausea and vomiting<br>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being | Compliance with Authority Required |

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| | | | | used to treat malignancy; AND<br>The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle; AND<br>Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND<br>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.<br>No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy. | procedures - Streamlined Authority Code 6937 |
| Nevirapine | C4454 | | | HIV infection<br>Continuing<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| | C4512 | | | HIV infection<br>Initial<br>Patient must be antiretroviral treatment naive; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4512 |
| | C4526 | | | HIV infection<br>Initial<br>Patient must have been stabilised on nevirapine immediate release; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4526 |
| Nicotine | C5140 | | | Nicotine dependence<br>Patient must be an Aboriginal or a Torres Strait Islander person. | |

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| | | | | The treatment must be the sole PBS-subsidised therapy for this condition. | |
| | C14040 | | | Nicotine dependence<br>The treatment must be as an aid to achieving abstinence from smoking; AND<br>The treatment must not be a PBS-benefit with other non-nicotine drugs that are PBS indicated for smoking cessation; AND<br>Patient must have indicated they are ready to cease smoking; AND<br>Patient must not receive more than 2 x 12-week PBS-subsidised treatment courses per 12 month period.<br>Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated.<br>Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated. | |
| Nilotinib | C12522 | | | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - third-line therapy<br>Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12522 |
| | C12529 | | | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - second-line therapy<br>The condition must be in the chronic phase; OR<br>The condition must be in the accelerated phase; AND<br>Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; AND | Compliance with Authority Required procedures |

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| | | | | Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; OR<br>Patient must have failed an adequate trial of PBS-subsidised first-line treatment with dasatinib for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Failure of an adequate trial of imatinib or dasatinib is defined as:<br>(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:<br>- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or<br>- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or<br>- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR<br>(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR<br>(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR<br>(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.<br>Accelerated phase is defined by the presence of 1 or more of the following:<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal | |

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| | | | | margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR<br>(v) Disease progression (defined as a greater than or equal to.<br>50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.<br>Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.<br>A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.<br>Pathology report(s) confirming a loss of response to imatinib or dasatinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records. | |
| | C12549 | | | Chronic Myeloid Leukaemia (CML)<br>Grandfather treatment for patients initiated with nilotinib 200 mg prior to 1 April 2012 as first-line therapy<br>The condition must be in the chronic phase; AND<br>Patient must have received PBS-subsidised treatment with nilotinib 200mg as a first-line therapy for this condition prior to 1 April 2012; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of | Compliance with Authority Required procedures - Streamlined Authority Code 12549 |

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| | | | | BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | |
| | C12557 | | | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy<br>Patient must have a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the chronic phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.<br>The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical | Compliance with Authority Required procedures |

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| | C12563 | | | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - second-line therapy<br>Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12563 |
| | C12569 | | | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - third-line therapy<br>The condition must be in the chronic phase; OR<br>The condition must be in the accelerated phase; AND<br>Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; OR<br>Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting; AND<br>Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; AND<br>Patient must have failed an adequate trial of PBS-subsidised second-line treatment with dasatinib for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Failure of an adequate trial of dasatinib is defined as: | Compliance with Authority Required procedures |

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| | | | | (i) Lack of response to second-line dasatinib therapy, defined as either:<br>- failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib for patients initially treated in chronic phase; or<br>- failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or<br>- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib; OR<br>(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib therapy; OR<br>(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib therapy; OR<br>(iv) Development of accelerated phase in a patient previously prescribed dasatinib for the chronic phase of chronic myeloid leukaemia.Accelerated phase is defined by the presence of 1 or more of the following:<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.<br>Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a | |

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| | | | | peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.<br>A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.<br>Pathology report(s) confirming a loss of response to imatinib and dasatinib, from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement must be documented in the patient's medical records. | |
| | C12572 | | | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - first-line therapy<br>The condition must be in the chronic phase; AND<br>Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; OR<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12572 |
| Nintedanib | C13378 | | | Idiopathic pulmonary fibrosis<br>Initial treatment 1 - new patient<br>The condition must be diagnosed through a multidisciplinary team; AND<br>Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis | Compliance with Written Authority Required procedures |

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| | | | | of idiopathic pulmonary fibrosis within the previous 12 months; AND<br>Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height; AND<br>Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND<br>Patient must not have had an acute respiratory infection at the time of FVC measurement; AND<br>Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%; AND<br>Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND<br>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.<br>A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.<br>Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.<br>Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) a completed authority prescription form; and | |

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| | | | | (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) | |
| | C13380 | | | Idiopathic pulmonary fibrosis<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND<br>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| | C13381 | | | Idiopathic pulmonary fibrosis<br>Initial treatment 2 - change or recommencement of treatment<br>Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND<br>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| | C13401 | | | Progressive fibrosing Interstitial lung disease<br>Initial treatment<br>The condition must be diagnosed through a multidisciplinary team; AND<br>The condition must have chest imaging through high resolution computed tomography (HRCT) that is no older than 12 months, to support the diagnosis of the PBS indication; AND | Compliance with Written Authority Required procedures |

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| | | | | The condition must display, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5); AND<br>Patient must have a current (no older than 2 years) forced vital capacity (FVC) measurement of no less than 45% predicted, adjusted for each of: (i) age, (ii) gender, (iii) height; AND<br>The condition must be of a progressive nature, observed by, in the 2 years leading up to this authority application, any of: (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records; AND<br>Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND<br>Patient must not have had an acute respiratory infection at the time of FVC measurement; AND<br>Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that is both: (i) at least 30% predicted, (ii) no greater than 80% predicted; AND<br>The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is); AND<br>The condition must not be due to reversible causes (e.g. drug toxicity).<br>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND<br>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.<br>Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.<br>If the application is submitted through HPOS form upload or mail, it must include: | |

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| | | | | (a) a completed authority prescription form; and<br>(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)<br>A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.<br>Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records. | |
| | C13412 | | | Progressive fibrosing Interstitial lung disease<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition.<br>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND<br>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| Niraparib | C13202 | P13202 | | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Initial treatment - first line treatment of a patient requiring a daily dose of up to 2 capsules<br>The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND<br>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<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition.<br>Patient must be undergoing treatment with this drug class for the first time; OR<br>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. | Compliance with Authority Required procedures |

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| | | | | 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.<br>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing. | |
| | C13204 | P13204 | | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Continuing treatment - first line treatment of a patient requiring a daily dose of 3 capsules<br>Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>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 |
| | C13264 | P13264 | | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Continuing treatment - first line treatment of a patient requiring a daily dose of up to 2 capsules<br>Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>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 |
| | C13273 | P13273 | | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Initial treatment - first line treatment of a patient requiring a daily dose of 3 capsules<br>The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND<br>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<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |

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| | | | | Patient must be undergoing treatment with this drug class for the first time; OR<br>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.<br>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.<br>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing. | |
| Nirmatrelvir and ritonavir | C13748 | | | SARS-CoV-2 infection<br>Patient must have received a positive polymerase chain reaction (PCR) test result; OR<br>Patient must have received a positive rapid antigen test (RAT) result; AND<br>Patient must have at least one sign or symptom attributable to COVID-19; AND<br>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND<br>The treatment must be initiated within 5 days of symptom onset.<br>Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk.<br>For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:<br>1. The patient is in residential aged care<br>2. The patient has disability with multiple comorbidities and/or frailty<br>3. Neurological conditions, including stroke and dementia and demyelinating conditions<br>4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease<br>5. Heart failure, coronary artery disease, cardiomyopathies<br>6. Obesity (BMI greater than 30 $kg/m^2$)<br>7. Diabetes type I or II, requiring medication for glycaemic control<br>8. Renal impairment (eGFR less than 60mL/min)<br>9. Cirrhosis<br>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<br>11. Past COVID-19 infection episode resulting in hospitalisation. | Compliance with Authority Required procedures - Streamlined Authority Code 13748 |

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| | | | | Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.<br>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.<br>Access to this drug through this restriction is permitted irrespective of vaccination status.<br>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.<br>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.<br>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | |
| | C13759 | | | SARS-CoV-2 infection<br>Patient must have received a positive polymerase chain reaction (PCR) test result; OR<br>Patient must have received a positive rapid antigen test (RAT) result; AND<br>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND<br>The treatment must be initiated within 5 days of symptom onset; OR<br>The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.<br>Patient must be at least 70 years of age.<br>Access to this drug through this restriction is permitted irrespective of vaccination status.<br>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.<br>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.<br>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | Compliance with Authority Required procedures - Streamlined Authority Code 13759 |
| | C13821 | | | SARS-CoV-2 infection<br>Patient must have received a positive polymerase chain reaction (PCR) test result; OR<br>Patient must have received a positive rapid antigen test (RAT) result; AND | Compliance with Authority Required procedures - |

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| | | | | Patient must have at least one sign or symptom attributable to COVID-19; AND<br>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND<br>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<br>The treatment must be initiated within 5 days of symptom onset.<br>Patient must be at least 18 years of age.<br>For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:<br>1. Any primary or acquired immunodeficiency including:<br>a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,<br>b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),<br>c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR<br>2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:<br>a. Chemotherapy or whole body radiotherapy,<br>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,<br>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),<br>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<br>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<br>4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR<br>5. People with disability with multiple comorbidities and/or frailty. | Streamlined Authority Code 13821 |

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| | | | | Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records<br>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.<br>Access to this drug through this restriction is permitted irrespective of vaccination status.<br>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.<br>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.<br>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | |
| | C14187 | | | SARS-CoV-2 infection<br>Patient must have received a positive polymerase chain reaction (PCR) test result; OR<br>Patient must have received a positive rapid antigen test (RAT) result; AND<br>Patient must have at least one sign or symptom attributable to COVID-19; AND<br>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND<br>The treatment must be initiated within 5 days of symptom onset.<br>Patient must be at high risk of requiring hospitalisation for COVID-19 infection; AND<br>Patient must be at least 50 years old, but not older than 60 years; OR<br>Patient must be at least 60 years old, but not older than 70 years.<br>For the purpose of administering this restriction, high risk is defined as the presence of at least one of the following conditions:<br>1. The patient is in residential aged care<br>2. The patient has disability with multiple comorbidities and/or frailty<br>3. Neurological conditions, including stroke and dementia and demyelinating conditions<br>4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease<br>5. Heart failure, coronary artery disease, cardiomyopathies<br>6. Obesity (BMI greater than 30 kg/m2)<br>7. Diabetes type I or II, requiring medication for glycaemic control | Compliance with Authority Required procedures - Streamlined Authority Code 14187 |

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| | | | | 8. Renal impairment (eGFR less than 60mL/min)<br>9. Cirrhosis<br>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<br>11. Past COVID-19 infection episode resulting in hospitalisation.<br>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.<br>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.<br>Access to this drug through this restriction is permitted irrespective of vaccination status.<br>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.<br>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.<br>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection. | |
| Nitrazepam | | P5661 | CN5661 | Malignant neoplasia (late stage) | Compliance with Authority Required procedures |
| | | P5771 | CN5771 | Myoclonic epilepsy | Compliance with Authority Required procedures |
| | | P5941 | CN5941 | Insomnia<br>Patient must be receiving this drug for the management of insomnia; AND<br>Patient must be receiving long-term nursing care; AND<br>Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult; AND<br>Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |

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| | | P5950 | CN5950 | Insomnia<br>Patient must be receiving this drug for the management of insomnia; AND<br>Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility; AND<br>Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
| | | P6175 | CN6175 | Insomnia<br>Patient must be receiving palliative care. | Compliance with Authority Required procedures |
| Nivolumab | C9216 | | | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx<br>Initial treatment<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy; AND<br>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor for this condition.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 9216 |
| | C9252 | | | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have stable or responding disease; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 9252 |

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| | C9298 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously been issued with an authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 9298 |
| | C9299 | | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 9299 |
| | C9312 | | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Initial Treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; OR<br>Patient must have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal; AND<br>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.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 9312 |

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| | C9321 | | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Maintenance treatment<br>Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND<br>The treatment must be as monotherapy for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.<br>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.<br>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 9321 |
| | C10119 | | | Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma<br>Initial treatment<br>The treatment must be adjuvant to complete surgical resection; AND<br>Patient must have a WHO performance status of 1 or less; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have received prior PBS-subsidised treatment for this condition; AND<br>The treatment must commence within 12 weeks of complete resection; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures |
| | C10120 | | | Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma<br>Continuing treatment<br>Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND<br>Patient must not have experienced disease recurrence; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks | Compliance with Authority Required procedures |

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| | | | | under a weight based or flat dosing regimen. | |
| | C10155 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Initial treatment<br>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<br>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<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 10155 |
| | C11468 | | | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing combination treatment (with ipilimumab) of first-line drug therapy<br>The condition must be squamous type non-small cell lung cancer (NSCLC); AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND<br>The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11468 |
| | C11477 | | | Locally advanced or metastatic non-small cell lung cancer<br>Continuing treatment as second-line drug therapy<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND<br>Patient must have stable or responding disease.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks | Compliance with Authority Required procedures - Streamlined Authority Code 11477 |

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| | | | | under a weight based or flat dosing regimen. | |
| | C11985 | | | Unresectable malignant mesothelioma<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be in combination with PBS-subsidised ipilimumab, unless an intolerance to ipilimumab of a severity necessitating permanent treatment withdrawal of ipilimumab; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must not exceed a maximum total of 24 months in a lifetime for this condition.<br>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 11985 |
| | C13433 | | | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial combination treatment (with ipilimumab) as first-line drug therapy<br>The condition must be squamous type non-small cell lung cancer (NSCLC); AND<br>Patient must not have previously been treated for this condition in the metastatic setting; OR<br>The condition must have progressed after treatment with tepotinib; AND<br>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<br>Patient must have a WHO performance status of 0 or 1; AND<br>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<br>The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND<br>The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 13433 |
| | C13445 | | | Locally advanced or metastatic non-small cell lung cancer<br>Initial treatment as second-line drug therapy<br>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<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 13445 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The condition must have progressed on or after prior platinum based chemotherapy; OR<br>The condition must have progressed after treatment with tepotinib.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.<br>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. | |
| | C13839 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Maintenance treatment<br>Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND<br>The treatment must be as monotherapy for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this PBS indication.<br>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.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 13839 |
| | C13852 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for combination induction therapy<br>Patient must have received non-PBS-subsidised treatment with nivolumab in combination with ipilimumab for this PBS indication prior to 1 March 2023; AND<br>Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to commencing non-PBS-subsidised treatment; AND<br>The condition must not be ocular or uveal melanoma; AND<br>The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.<br>Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.<br>Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. | Compliance with Authority Required procedures - Streamlined Authority Code 13852 |

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| | C13853 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Induction treatment<br>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<br>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND<br>The condition must not be ocular or uveal melanoma; AND<br>The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.<br>Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.<br>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 13853 |
| | C13863 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for maintenance treatment<br>Patient must have previously received of up to maximum 4 doses of PBS-subsidised ipilimumab combined therapy with non-PBS-subsidised nivolumab as induction for this condition prior to 1 March 2023; AND<br>The treatment must be as monotherapy for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this PBS indication.<br>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.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 13863 |
| | C13888 | | | Advanced or metastatic gastro-oesophageal cancers<br>The condition must be a gastro-oesophageal cancer type as specified in the drug's 'Indications' section of the approved Australian Product Information; AND<br>The treatment must be prescribed in accordance with the drug's 'Indications' section of the | Compliance with Authority Required procedures - Streamlined Authority |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | approved Australian Production Information with respect to each of: (i) concomitant drugs/therapies, (ii) line of therapy (i.e. prior treatments, if any); AND<br>Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND<br>Patient must be untreated with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer.<br>Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs. | Code 13888 |
| | C13900 | | | Adjuvant treatment of stage II or III oesophageal cancer or gastro-oesophageal junction cancer<br>The condition must have histological evidence confirming a diagnosis of a least one of: (i) adenocarcinoma, (ii) squamous cell cancer; document this evidence in the patient's medical records; AND<br>The condition must have been treated with neoadjuvant platinum-based chemoradiotherapy; AND<br>The treatment must be for the purposes of adjuvant use following complete surgical resection that occurred within 16 weeks prior to initiating this drug; AND<br>The condition must have evidence, through resected specimen, that residual disease meets the Tumour Nodes Metastases (TNM) staging system (as published by the Union for International Cancer Control) of either: (i) at least ypT1, (ii) at least ypN1; document this evidence in the patient's medical records; AND<br>Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patient must be undergoing treatment with a dosing regimen as set out in the drug's approved Australian Product Information; AND<br>Patient must not be undergoing PBS-subsidised treatment with this drug where this prescription extends treatment beyond whichever comes first: (i) 12 months from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease recurrence despite treatment with this drug; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs. | Compliance with Authority Required procedures |

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| | C14001 | | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Induction treatment<br>The condition must not have previously been treated; AND<br>Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.<br>Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 14001 |
| Norfloxacin | C5744 | | | Acute bacterial enterocolitis | Compliance with Authority Required procedures |
| | C5806 | | | Complicated urinary tract infection | Compliance with Authority Required procedures |
| Nortriptyline | C6235 | | | Major depression<br>The treatment must be for use when other anti-depressant therapy has failed. | |
| | C6300 | | | Major depression<br>The treatment must be for use when other anti-depressant therapy is contraindicated. | |
| Obeticholic acid | C12084 | | | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)<br>Initial treatment<br>Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR<br>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 | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | pharmaceutical benefit on this occasion; AND<br>Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR<br>Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.<br>Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; OR<br>Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug; AND<br>Patient must not have/be each of: (i) severe liver disease, (ii) immunocompromised; AND<br>Patient must have an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) having accounted for each of: (i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR<br>Patient must have a total bilirubin level between 1 to 2 times the ULN, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR<br>Patient must have abnormal readings of at least one of: (i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid.<br>Patient must be aged 18 years or older.<br>Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction. | |
| | C12138 | | | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)<br>Continuing treatment<br>Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR<br>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<br>Patient must be undergoing continuing PBS-subsidised treatment with this drug, with treatment having commenced through one of: (i) the 'Initial treatment' listing, (ii) 'Grandfather' arrangements; AND | Compliance with Authority Required procedures - Streamlined Authority Code 12138 |

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| | | | | Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR<br>Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.<br>Patient must have achieved an adequate response to this drug, defined as having at least one of: (i) an alkaline phosphate (ALP) level less than 1.67 times the upper limit of normal (ULN), (ii) a reduction in the ALP reading of at least 15% compared to the baseline level provided with the initial authority application, (iii) a total bilirubin level within the normal reference range.<br>The improvement in the qualifying laboratory reading(s) has/have been documented in the patient's medical records. | |
| | C12140 | | | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)<br>Transitioning from non-PBS to PBS subsidised supply - Grandfather arrangements<br>Must be treated by a prescriber who is either: (i) a gastroenterologist, (ii) a hepatologist; OR<br>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<br>Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; OR<br>Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated.<br>Patient must have received treatment with this drug for this PBS indication prior to 1 September 2021; AND<br>Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; OR<br>Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug; AND<br>Patient must not have/be each of: (i) severe liver disease, (ii) immunocompromised; AND<br>Patient must have had, prior to initiating treatment with this drug, an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) having accounted for each of: (i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR | Compliance with Authority Required procedures |

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| | | | | Patient must have had, prior to initiating treatment with this drug, a total bilirubin level between 1 to 2 times the ULN, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; OR<br>Patient must have had, prior to initiating treatment with this drug, abnormal readings of at least one of: (i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid.<br>Patient must be aged 18 years or older.<br>Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction. | |
| Obinutuzumab | C11015 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>For combination use with venetoclax treatment cycles 1 to 6 inclusive in first-line therapy<br>The condition must be untreated; AND<br>The treatment must be in combination with PBS-subsidised venetoclax. | Compliance with Authority Required procedures - Streamlined Authority Code 11015 |
| | C11052 | | | Chronic lymphocytic leukaemia (CLL)<br>Combination use with chlorambucil only<br>The condition must be CD20 positive; AND<br>The condition must be previously untreated; AND<br>Patient must be inappropriate for fludarabine based chemo-immunotherapy; AND<br>The treatment must be in combination with chlorambucil; AND<br>Patient must have a creatinine clearance 30 mL/min or greater; AND<br>Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); OR<br>Patient must have a creatinine clearance less than 70 mL/min.<br>Treatment must be discontinued in patients who experience disease progression whilst on this treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 11052 |
| | C11755 | | | Follicular lymphoma<br>Re-induction treatment<br>Patient must not have previously received PBS-subsidised obinutuzumab; AND<br>The condition must be CD20 positive; AND<br>The condition must be refractory to treatment with rituximab for this condition; AND | Compliance with Authority Required procedures |

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| | | | | The condition must be symptomatic; AND<br>The treatment must be for re-induction treatment purposes only; AND<br>The treatment must be in combination with bendamustine; AND<br>The treatment must not exceed 8 doses for re-induction treatment with this drug for this condition.<br>The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.<br>A patient may only qualify for PBS-subsidised initiation treatment once in a lifetime under:<br>i) the previously untreated induction treatment restriction; or<br>ii) the rituximab-refractory re-induction restriction. | |
| | C11785 | | | Follicular lymphoma<br>Maintenance therapy<br>Patient must have previously received PBS-subsidised treatment with this drug under the rituximab refractory initial restriction; AND<br>The condition must be CD20 positive; AND<br>The condition must have been refractory to treatment with rituximab; AND<br>Patient must have demonstrated a partial or complete response to PBS-subsidised re-induction treatment with this drug for this condition; AND<br>The treatment must be maintenance therapy; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| | C11787 | | | Stage II bulky or Stage III/IV follicular lymphoma<br>Maintenance therapy<br>Patient must have previously received PBS-subsidised treatment with this drug under the previously untreated initial restriction; AND<br>The condition must be CD20 positive; AND<br>Patient must have demonstrated a partial or complete response to PBS subsidised induction treatment with this drug for this condition; AND | Compliance with Authority Required procedures |

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| | | | | The treatment must be maintenance therapy; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | |
| | C11815 | | | Stage II bulky or Stage III/IV follicular lymphoma<br>Induction treatment<br>The condition must be CD20 positive; AND<br>The condition must be previously untreated; AND<br>The condition must be symptomatic; AND<br>The treatment must be for induction treatment purposes only; AND<br>The treatment must be in combination with chemotherapy; AND<br>The treatment must not exceed 10 doses for induction treatment with this drug for this condition.<br>A patient may only qualify for PBS-subsidised initiation treatment once in a lifetime under:<br>i) the previously untreated induction treatment restriction; or<br>ii) the rituximab-refractory re-induction restriction. | Compliance with Authority Required procedures |
| Ocrelizumab | C7386 | | | Multiple sclerosis<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy.<br>Must be treated by a neurologist. | Compliance with Authority Required procedures - Streamlined Authority Code 7386 |
| | C7699 | | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Must be treated by a neurologist.<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Code 7699 |
| | C9523 | | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Must be treated by a neurologist.<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9523 |
| | C9635 | | | Multiple sclerosis<br>Continuing treatment | Compliance with Authority Required |

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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy.<br>Must be treated by a neurologist. | procedures - Streamlined Authority Code 9635 |
| Ocriplasmin | C9363 | | | Vitreomacular traction syndrome<br>Must be treated by an ophthalmologist.<br>Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH); OR<br>Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres; AND<br>Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment; AND<br>The condition must be diagnosed by optical coherence tomography; AND<br>The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres; AND<br>Patient must not have an epiretinal membrane attached to the vitreomacular traction; AND<br>The condition must be previously untreated in the eye proposed for treatment; AND<br>Patient must not have received prior vitrectomy in the eye proposed for treatment; AND<br>Patient must be symptomatic.<br>The prescriber must state which eye(s) is being treated at the time of application. | Compliance with Authority Required procedures |
| Octreotide | C5901 | | | Functional carcinoid tumour<br>Patient must have achieved symptom control on octreotide immediate release injections; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 5901 |

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| | C5906 | | | Vasoactive intestinal peptide secreting tumour (VIPoma)<br>Patient must have achieved symptom control on octreotide immediate release injections; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 5906 |
| | C6369 | | | Vasoactive intestinal peptide secreting tumour (VIPoma)<br>The condition must be causing intractable symptoms; AND<br>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND<br>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 6369 |
| | C6390 | | | Functional carcinoid tumour<br>The condition must be causing intractable symptoms; AND<br>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND<br>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 6390 |
| | C8161 | | | Acromegaly | Compliance with |

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| | | | | The condition must be controlled with octreotide immediate release injections; AND<br>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND<br>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.<br>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Authority Required procedures - Streamlined Authority Code 8161 |
| | C8165 | | | Acromegaly<br>The condition must be active; AND<br>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND<br>The treatment must be after failure of other therapy including dopamine agonists; OR<br>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR<br>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND<br>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND<br>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.<br>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Authority Required procedures - Streamlined Authority Code 8165 |
| | C8197 | | | Acromegaly<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The condition must be controlled with octreotide immediate release injections; AND<br>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence | Compliance with Authority Required procedures - Streamlined Authority Code 8197 |

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| | | | | of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND<br>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.<br>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | |
| | C8198 | | | Vasoactive intestinal peptide secreting tumour (VIPoma)<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have achieved symptom control on octreotide immediate release injections; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 8198 |
| | C8208 | | | Functional carcinoid tumour<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have achieved symptom control on octreotide immediate release injections; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 8208 |
| | C9232 | | | Vasoactive intestinal peptide secreting tumour (VIPoma)<br>The condition must be causing intractable symptoms; AND<br>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND<br>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; | Compliance with Authority Required procedures - Streamlined Authority Code 9232 |

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| | | | | AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | |
| | C9233 | | | Acromegaly<br>The condition must be active; AND<br>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND<br>The treatment must be after failure of other therapy including dopamine agonists; OR<br>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR<br>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND<br>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND<br>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.<br>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Authority Required procedures - Streamlined Authority Code 9233 |
| | C9262 | | | Acromegaly<br>The condition must be controlled with octreotide immediate release injections; AND<br>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND<br>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND<br>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.<br>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 | Compliance with Authority Required procedures - Streamlined Authority Code 9262 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | years after radiotherapy for assessment of remission | |
| | C9288 | | | Vasoactive intestinal peptide secreting tumour (VIPoma)<br>Patient must have achieved symptom control on octreotide immediate release injections; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 9288 |
| | C9289 | | | Functional carcinoid tumour<br>The condition must be causing intractable symptoms; AND<br>Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND<br>Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 9289 |
| | C9313 | | | Functional carcinoid tumour<br>Patient must have achieved symptom control on octreotide immediate release injections; AND<br>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.<br>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 9313 |
| | C10061 | | | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.<br>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Code 10061 |
| | C10075 | | | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.<br>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Compliance with Authority Required procedures - Streamlined Authority Code 10075 |
| | C10077 | | | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.<br>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Compliance with Authority Required procedures - Streamlined Authority Code 10077 |
| Ofatumumab | C10162 | P10162 | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging | Compliance with Authority Required procedures - Streamlined Authority Code 10162 |

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| | | | | scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | |
| | C10172 | P10172 | | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10172 |
| Ofloxacin | C4181 | | | Bacterial keratitis<br>Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | Compliance with Authority Required procedures |
| | C4195 | | | Bacterial keratitis<br>Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | Compliance with Authority Required procedures |
| Olanzapine | C4304 | | | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 4304 |
| | C5856 | | | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 5856 |
| | C5869 | | | Bipolar I disorder<br>The treatment must be maintenance therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5869 |
| Olaparib | C10913 | P10913 | | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Continuing treatment - first line treatment<br>Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response. | Compliance with Authority Required procedures |
| | C10937 | P10937 | | High grade epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Continuing treatment - second line treatment<br>Patient must have previously received PBS-subsidised treatment with this drug as a second line therapy for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must be maintenance therapy; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>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 | Compliance with Authority Required procedures - Streamlined Authority Code 10937 |

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| | | | | Tumours (RECIST) guidelines. | |
| | C10958 | P10958 | | High grade epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Initial treatment - second line treatment<br>The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND<br>The condition must be platinum sensitive; AND<br>Patient must have received at least two previous platinum-containing regimens; AND<br>Patient must have relapsed following a previous platinum-containing regimen; AND<br>Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must be maintenance therapy; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition.<br>Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.<br>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.<br>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing. | Compliance with Authority Required procedures |
| | C12590 | P12590 | | Castration resistant metastatic carcinoma of the prostate<br>Initial treatment<br>The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND<br>The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug; AND<br>The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease); AND<br>Patient must have a WHO performance status of 2 or less.<br>Patient must be undergoing treatment with this drug for the first time. | Compliance with Authority Required procedures |
| | C12598 | P12598 | | Castration resistant metastatic carcinoma of the prostate<br>Continuing treatment | Compliance with Authority Required |

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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>The treatment must not be subsidised in combination with: (i) chemotherapy, (ii) a novel hormonal drug. | procedures |
| | C13226 | P13226 | | High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Initial treatment - first line treatment<br>The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND<br>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<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition.<br>Patient must be undergoing treatment with this drug class for the first time; OR<br>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.<br>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.<br>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing. | Compliance with Authority Required procedures |
| Olmesartan with amlodipine | C4373 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>The condition must be inadequately controlled with an angiotensin II antagonist; OR<br>The condition must be inadequately controlled with a dihydropyridine calcium channel blocker. | |
| Olmesartan with amlodipine and hydrochlorothiazide | C4311 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>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 | |

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| | | | | diuretic. | |
| Olmesartan with hydrochlorothiazide | C4374 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>The condition must be inadequately controlled with an angiotensin II antagonist; OR<br>The condition must be inadequately controlled with a thiazide diuretic. | |
| Olsalazine | C4824 | | | Ulcerative colitis<br>Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR<br>Patient must be intolerant to sulfasalazine. | Compliance with Authority Required procedures - Streamlined Authority Code 4824 |
| Omeprazole | C5444 | | | Gastro-oesophageal reflux disease | |
| | C5512 | | | Scleroderma oesophagus | |
| | C5529 | | | Zollinger-Ellison syndrome | |
| | C8774 | P8774 | | Gastro-oesophageal reflux disease<br>The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR<br>The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease. | Compliance with Authority Required procedures - Streamlined Authority Code 8774 |
| | C8775 | P8775 | | Peptic ulcer<br>Initial treatment<br>Patient must have tested negative for helicobacter pylori infection; OR<br>Patient must have failed treatment with helicobacter pylori eradication therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 8775 |
| | C8776 | P8776 | | Gastro-oesophageal reflux disease<br>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 |

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| | | | | | Code 8776 |
| | C8780 | P8780 | | Scleroderma oesophagus | Compliance with Authority Required procedures - Streamlined Authority Code 8780 |
| | C8866 | P8866 | | Zollinger-Ellison syndrome | Compliance with Authority Required procedures - Streamlined Authority Code 8866 |
| | C11310 | P11310 | | Complex gastro-oesophageal reflux disease (GORD)<br>One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control<br>Must be treated by a gastroenterologist; OR<br>Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR<br>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<br>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.<br>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<br>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<br>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 | Compliance with Authority Required procedures |

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| | | | | 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<br>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.<br>Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction. | |
| Ondansetron | C4102 | P4102 | | Nausea and vomiting<br>The condition must be associated with radiotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 4102 |
| | C4118 | P4118 | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.<br>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. | |
| | C5618 | P5618 | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.<br>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. | |
| | C5721 | P5721 | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.<br>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. | |
| | C5743 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.<br>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. | |

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| | C5778 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.<br>Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle. | |
| | C10498 | P10498 | | Nausea and vomiting<br>The condition must be associated with radiotherapy being used to treat malignancy; OR<br>The condition must be associated with oral chemotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 10498 |
| Opicapone | C5133 | | | Parkinson disease<br>The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination; AND<br>Patient must be experiencing fluctuations in motor function due to end-of-dose effect. | |
| Osimertinib | C11178 | | | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy<br>Patient must not have previously received this drug for this condition; AND<br>The treatment must be as monotherapy; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>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<br>Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment. | Compliance with Authority Required procedures |
| | C11181 | | | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy<br>The treatment must be as monotherapy; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures |

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| | | | | Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed). | |
| | C11183 | | | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed). | Compliance with Authority Required procedures |
| | C11185 | | | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR<br>Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.<br>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. | Compliance with Authority Required procedures |
| Oxazepam | | P6176 | CN6176 | Anxiety<br>Patient must be receiving palliative care. | Compliance with Authority Required procedures |

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| | | P6217 | CN6217 | Malignant neoplasia (late stage) | Compliance with Authority Required procedures |
| | | P6230 | CN6230 | Anxiety<br>Patient must be receiving this drug for the management of anxiety; AND<br>Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility; AND<br>Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
| | | P6262 | CN6262 | Anxiety<br>Patient must be receiving this drug for the management of anxiety; AND<br>Patient must be receiving long-term nursing care; AND<br>Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult; AND<br>Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
| Oxcarbazepine | C5183 | | | Seizures<br>Patient must have partial epileptic seizures; OR<br>Patient must have primary generalised tonic-clonic seizures; AND<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 5183 |
| Oxybutynin | C6241 | | | Detrusor overactivity | |
| | C6243 | | | Detrusor overactivity<br>Patient must be unable to tolerate oral oxybutynin; OR<br>Patient must be unable to swallow oral oxybutynin. | |
| Oxycodone | C10748 | P10748 | | Chronic severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>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:<br>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Code 10748 |
| | C10752 | P10752 | | Chronic severe pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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:<br>(i) is less than 12 months; or<br>(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management | Compliance with Authority Required procedures - Streamlined Authority Code 10752 |

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| | | | | review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10755 | P10755 | | Chronic severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures - Streamlined Authority Code 10755 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | C10764 | P10764 | | Severe pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:<br>(i) severe disabling pain associated with malignant neoplasia; or<br>(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or<br>(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<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10766 | P10766 | | Severe pain<br>The treatment must be for short term therapy of acute severe pain; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. | |
| | C10768 | P10768 | | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. | |
| | C10771 | P10771 | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10772 | P10772 | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.<br>Authorities for increased maximum quantities and/or repeats must only be considered for:<br>(i) severe disabling pain associated with proven malignant neoplasia; or<br>(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 | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10860 | | | Severe pain<br>The treatment must be for post-operative pain following a major operative procedure; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. | |
| | C10890 | | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have cancer pain; OR<br>The treatment must be for post-operative pain following a major operative procedure; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.<br>Authorities for increased maximum quantities and/or repeats must only be considered for:<br>(i) severe disabling pain associated with proven malignant neoplasia; or | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (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<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10910 | | | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have cancer pain; OR<br>The treatment must be for post-operative pain following a major operative procedure; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the | |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C11753 | P11753 | | Severe disabling pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>Patient must be undergoing palliative care.<br>Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures |
| Oxycodone with naloxone | C10748 | P10748 | | Chronic severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>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:<br>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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 | Compliance with Authority Required procedures - Streamlined Authority Code 10748 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | |
| | C10752 | P10752 | | Chronic severe pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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:<br>(i) is less than 12 months; or<br>(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or<br>(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<br>(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.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. | Compliance with Authority Required procedures - Streamlined Authority Code 10752 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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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). | |
| | C10755 | P10755 | | Chronic severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain; OR<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>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.<br>Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures - Streamlined Authority Code 10755 |
| | C11753 | P11753 | | Severe disabling pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>Patient must be undergoing palliative care.<br>Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.<br>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). | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| Ozanimod | C10162 | P10162 | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10162 |
| | C10172 | P10172 | | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10172 |
| | C13946 | P13946 | | Moderate to severe ulcerative colitis<br>Continuing treatment - balance of supply<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (code 82)].<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | |
| | C13993 | P13993 | | Moderate to severe ulcerative colitis<br>Transitioning from non-PBS to PBS-subsided treatment - Grandfather arrangements<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2023; AND<br>Patient must be receiving treatment with this drug for this condition at the time of application; AND<br>The condition must have responded inadequately to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for at least 3 consecutive months prior to treatment initiation with this drug; OR<br>Patient must have experienced a severe intolerance to the above therapy leading to permanent treatment discontinuation; AND<br>The condition must have responded inadequately to azathioprine at a dose of at least 2 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR<br>The condition must have responded inadequately to 6-mercaptopurine at a dose of at least 1 mg per kg daily for at least 3 consecutive months prior to treatment initiation with this drug; OR<br>The condition must have responded inadequately to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, followed by an inadequate response to at least 3 consecutive months of treatment with an appropriately dosed thiopurine agent, prior to treatment initiation with this drug; OR<br>Patient must have experienced a severe intolerance to each of the above 3 therapies leading to permanent treatment discontinuation; AND<br>Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non- | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | PBS-subsidised treatment with this drug for this condition; OR<br>Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR<br>Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a 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:<br>(i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) including the date of assessment;<br>(ii) the date of commencement of this drug.<br>A patient may qualify for PBS-subsidised treatment under this restriction once only.<br>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.<br>The assessment of the patient's response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.<br>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.<br>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. | |
| | C13995 | P13995 | | Moderate to severe ulcerative colitis | Compliance with Written |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Initial treatment - Initial 1 (new patient)<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND<br>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR<br>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR<br>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND<br>Patient must have a Mayo clinic score greater than or equal to 6; OR<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a 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:<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and<br>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]. | Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.<br>An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.<br>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.<br>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.<br>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>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.<br>A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | |
| | C14002 | P14002 | | Moderate to severe ulcerative colitis<br>Continuing treatment<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug. | Compliance with Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be at least 18 years of age.<br>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>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.<br>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.<br>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.<br>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. | |
| | C14003 | P14003 | | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this | Compliance with Written Authority Required procedures |

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| | | | | condition in this treatment cycle; AND<br>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.<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a 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:<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.<br>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.<br>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.<br>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.<br>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.<br>A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | |
| | C14004 | P14004 | | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); OR | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>Patient must have a Mayo clinic score greater than or equal to 6; OR<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).<br>Patient must be at least 18 years of age.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a 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:<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.<br>An assessment of a patient's response to this initial course of treatment must be conducted between 9 and 17 weeks of therapy.<br>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.<br>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. | |

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| | | | | A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | |
| | C14005 | P14005 | | Moderate to severe ulcerative colitis<br>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<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].<br>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<br>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<br>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<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| | C14017 | | | Moderate to severe ulcerative colitis<br>Dose escalation occurring at initial treatment or re-initiation of treatment<br>Must be treated by a gastroenterologist (code 87); OR<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. | Compliance with Authority Required procedures - Streamlined Authority Code 14017 |
| Paclitaxel, nanoparticle albumin-bound | C4657 | | | Stage IV (metastatic) adenocarcinoma of the pancreas<br>The treatment must be in combination with gemcitabine; AND<br>The condition must not have been treated previously with PBS-subsidised therapy; AND<br>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | 2 or less.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Code 4657 |
| | C6106 | | | Metastatic breast cancer | Compliance with Authority Required procedures - Streamlined Authority Code 6106 |
| | C6119 | | | HER2 positive breast cancer | Compliance with Authority Required procedures - Streamlined Authority Code 6119 |
| Palbociclib | C13055 | | | Locally advanced or metastatic breast cancer<br>Initial treatment<br>Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR<br>Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND<br>The condition must be hormone receptor positive; AND<br>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND<br>The condition must be inoperable; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND<br>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<br>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<br>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. | Compliance with Authority Required procedures |

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| | | | | Patient must not be premenopausal. | |
| | C13066 | | | Locally advanced or metastatic breast cancer<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND<br>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.<br>Patient must not be premenopausal.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures |
| Paliperidone | C4246 | | | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 4246 |
| | C13049 | | | Schizophrenia<br>Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months; OR<br>Patient must have previously received and be stabilised on PBS-subsidised paliperidone six-monthly injection for at least one cycle. | Compliance with Authority Required procedures - Streamlined Authority Code 13049 |
| | C13082 | | | Schizophrenia<br>Patient must have previously received and be stabilised on PBS-subsidised paliperidone three-monthly injection for at least one cycle; OR<br>Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months. | Compliance with Authority Required procedures - Streamlined Authority Code 13082 |

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| Palonosetron | C5686 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| | C5805 | | | Nausea and vomiting<br>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| Pamidronic acid | C4433 | | | Hypercalcaemia of malignancy<br>Patient must have a malignancy refractory to anti-neoplastic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 4433 |
| | C4877 | | | Symptomatic Paget disease of bone | |
| | C5218 | | | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 5218 |
| | C5291 | | | Bone metastases<br>The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 5291 |
| | C9234 | | | Hypercalcaemia of malignancy<br>Patient must have a malignancy refractory to anti-neoplastic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 9234 |

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| | C9315 | | | Bone metastases<br>The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 9315 |
| | C9335 | | | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 9335 |
| Pancreatic extract | | P5779 | | Cystic fibrosis<br>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. | |
| Pancrelipase | | P5779 | | Cystic fibrosis<br>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. | |
| Panitumumab | C5452 | | | Metastatic colorectal cancer<br>Continuing treatment<br>Patient must have received an initial authority prescription for panitumumab for first-line treatment of RAS wild-type metastatic colorectal cancer; AND<br>Patient must not have progressive disease; AND<br>The treatment must be in combination with first-line chemotherapy; AND<br>The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.<br>Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.<br>Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab. | Compliance with Authority Required procedures - Streamlined Authority Code 5452 |

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| | C5526 | | | Metastatic colorectal cancer<br>Initial Treatment<br>Patient must have RAS wild-type metastatic colorectal cancer; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>The condition must be previously untreated; AND<br>The treatment must be in combination with first-line chemotherapy; AND<br>The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.<br>Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.<br>Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab. | Compliance with Authority Required procedures - Streamlined Authority Code 5526 |
| | C12035 | | | Metastatic colorectal cancer<br>Continuing treatment<br>Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; OR<br>Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC; AND<br>Patient must not have progressive disease; AND<br>The treatment must be as monotherapy; OR<br>The treatment must be in combination with chemotherapy; AND<br>The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.<br>Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.<br>Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab. | Compliance with Authority Required procedures - Streamlined Authority Code 12035 |
| | C12066 | | | Metastatic colorectal cancer<br>Initial treatment<br>Patient must have RAS wild-type metastatic colorectal cancer; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The condition must have failed to respond to first-line chemotherapy; OR | Compliance with Authority Required procedures - Streamlined Authority Code 12066 |

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| | | | | The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC; AND<br>The treatment must be as monotherapy; OR<br>The treatment must be in combination with chemotherapy; AND<br>The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.<br>Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.<br>Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab. | |
| Pantoprazole | C5444 | | | Gastro-oesophageal reflux disease | |
| | C5512 | | | Scleroderma oesophagus | |
| | C5529 | | | Zollinger-Ellison syndrome | |
| | C8774 | P8774 | | Gastro-oesophageal reflux disease<br>The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR<br>The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease. | Compliance with Authority Required procedures - Streamlined Authority Code 8774 |
| | C8775 | P8775 | | Peptic ulcer<br>Initial treatment<br>Patient must have tested negative for helicobacter pylori infection; OR<br>Patient must have failed treatment with helicobacter pylori eradication therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 8775 |
| | C8776 | P8776 | | Gastro-oesophageal reflux disease<br>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 8776 |

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| | C8780 | P8780 | | Scleroderma oesophagus | Compliance with Authority Required procedures - Streamlined Authority Code 8780 |
| | C8866 | P8866 | | Zollinger-Ellison syndrome | Compliance with Authority Required procedures - Streamlined Authority Code 8866 |
| | C11310 | P11310 | | Complex gastro-oesophageal reflux disease (GORD)<br>One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control<br>Must be treated by a gastroenterologist; OR<br>Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR<br>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<br>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.<br>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<br>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<br>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<br>Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; | Compliance with Authority Required procedures |

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| | | | | treatment is for: (3) re-establishment of symptom control; OR<br>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.<br>Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction. | |
| Paracetamol | C5835 | P5835 | | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| | C5846 | P5846 | | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| | C5865 | P5865 | | Chronic arthropathies<br>Patient must identify as Aboriginal or Torres Strait Islander. | |
| | C5885 | P5885 | | Chronic arthropathies<br>Patient must identify as Aboriginal or Torres Strait Islander. | |
| | C6167 | | | Analgesia or fever<br>Patient must be receiving palliative care; AND<br>Patient must be intolerant to alternative therapy. | |
| | C6225 | P6225 | | Analgesia or fever<br>Patient must be receiving palliative care; AND<br>Patient must be intolerant to alternative therapy. | |
| | C6280 | P6280 | | Persistent pain<br>The condition must be associated with osteoarthritis.<br>Patient must identify as Aboriginal or Torres Strait Islander. | |
| Paraffin | | P4894 | | For use in patients who are 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. | |
| | | P5713 | | For use in patients who are 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 | |

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| | | | | coordination of the Arrangements. | |
| | C6172 | | | Severe dry eye syndrome<br>Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 6172 |
| Paraffin with retinol palmitate | | P4072 | | For use in patients who are 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. | |
| Paroxetine | C4755 | | | Major depressive disorders | |
| | C6277 | | | Obsessive-compulsive disorder | |
| | C6636 | | | Panic disorder | |
| Pazopanib | C7458 | P7458 | | Advanced (unresectable and/or metastatic) soft tissue sarcoma<br>Continuing treatment beyond 3 months<br>Patient must have received an initial authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7458 |
| | C7459 | P7459 | | Advanced (unresectable and/or metastatic) soft tissue sarcoma<br>Continuing treatment beyond 3 months<br>Patient must have received an initial authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND<br>Patient must require dose adjustment; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7459 |
| | C9247 | P9247 | | Advanced (unresectable and/or metastatic) soft tissue sarcoma<br>Initial treatment | Compliance with Authority Required |

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| | | | | Patient must have a WHO performance status of 2 or less; AND<br>Patient must have received prior chemotherapy treatment including an anthracycline; AND<br>Patient must not have received prior treatment with an angiogenesis inhibitor; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patient must not have any of the following conditions:<br>adipocytic soft tissue sarcoma;<br>gastrointestinal stromal tumour (GIST);<br>rhabdomyosarcoma other than alveolar or pleomorphic;<br>chondrosarcoma;<br>osteosarcoma;<br>Ewings tumour/primitive neuroectodermal tumour;<br>dermofibromatosis sarcoma protuberans;<br>inflammatory myofibroblastic sarcoma;<br>malignant mesothelioma;<br>mixed mesodermal tumour of the uterus. | procedures - Streamlined Authority Code 9247 |
| | C11937 | P11937 | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Continuing treatment beyond 3 months<br>Patient must have received an initial authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib. | Compliance with Authority Required procedures - Streamlined Authority Code 11937 |
| | C11939 | P11939 | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Continuing treatment beyond 3 months<br>Patient must have received an initial authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND | Compliance with Authority Required procedures - Streamlined Authority Code 11939 |

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| | | | | Patient must require dose adjustment; AND<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib. | |
| | C11974 | P11974 | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Initial treatment<br>The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of: (i) cabozantinib, (ii) pazopanib, (iii) sunitinib. | Compliance with Authority Required procedures - Streamlined Authority Code 11974 |
| Pegfilgrastim | C7822 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must be at greater than 20% risk of developing febrile neutropenia; OR<br>Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 7822 |
| | C7843 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must have had a prior episode of febrile neutropenia; OR<br>Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 7843 |
| | C9235 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial | Compliance with Authority Required |

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| | | | | remission; AND<br>Patient must be at greater than 20% risk of developing febrile neutropenia; OR<br>Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | procedures - Streamlined Authority Code 9235 |
| | C9303 | | | Chemotherapy-induced neutropenia<br>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND<br>Patient must have had a prior episode of febrile neutropenia; OR<br>Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 9303 |
| Peginterferon alfa-2a | | P5004 | CN5004 | Chronic hepatitis C infection<br>Must be treated in an accredited treatment centre.<br>Patient must be aged 18 years or older; AND<br>Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.<br>Patient must have compensated liver disease; AND<br>Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND<br>Patient must have a contraindication to ribavirin; AND<br>The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND<br>The treatment must be limited to a maximum duration of 48 weeks.<br>Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5004 |
| | | P9603 | CN9603 | Chronic hepatitis C infection<br>Must be treated in an accredited treatment centre.<br>Patient must be aged 18 years or older; AND<br>Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.<br>Patient must have compensated liver disease; AND | Compliance with Authority Required procedures - Streamlined Authority Code 9603 |

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| | | | | Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND<br>Patient must have a contraindication to ribavirin; AND<br>The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND<br>The treatment must be limited to a maximum duration of 48 weeks.<br>Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. | |
| Peginterferon beta-1a | C6860 | P6860 | | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6860 |
| | C7695 | P7695 | | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7695 |
| Pembrolizumab | C10676 | | | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma<br>Continuing treatment - 6 weekly treatment regimen | Compliance with Authority Required |

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| | | | | Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND<br>Patient must not have experienced disease recurrence; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | procedures |
| | C10687 | | | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma<br>Initial treatment - 3 weekly treatment regimen<br>The treatment must be adjuvant to complete surgical resection; AND<br>Patient must have a WHO performance status of 1 or less; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have received prior PBS-subsidised treatment for this condition; AND<br>The treatment must commence within 12 weeks of complete resection; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| | C10688 | | | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma<br>Initial treatment - 6 weekly treatment regimen<br>The treatment must be adjuvant to complete surgical resection; AND<br>Patient must have a WHO performance status of 1 or less; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have received prior PBS-subsidised treatment for this condition; AND<br>The treatment must commence within 12 weeks of complete resection; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| | C10689 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Initial treatment - 6 weekly treatment regimen<br>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<br>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 | Compliance with Authority Required procedures - Streamlined Authority Code 10689 |

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| | | | | treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not exceed a total of 3 doses under this restriction. | |
| | C10695 | | | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma<br>Continuing treatment - 3 weekly treatment regimen<br>Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND<br>Patient must not have experienced disease recurrence; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| | C10696 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Initial treatment - 3 weekly treatment regimen<br>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<br>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<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not exceed a total of 6 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 10696 |
| | C10701 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Continuing treatment - 6 weekly treatment regimen<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously been issued with an authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10701 |
| | C10705 | | | Unresectable Stage III or Stage IV malignant melanoma<br>Continuing treatment - 3 weekly treatment regimen<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND | Compliance with Authority Required procedures - |

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| | | | | Patient must have previously been issued with an authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease. | Streamlined Authority Code 10705 |
| | C13431 | | | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment - 3 weekly treatment regimen<br>Patient must not have previously been treated for this condition in the metastatic setting; OR<br>The condition must have progressed after treatment with tepotinib; AND<br>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<br>Patient must have a WHO performance status of 0 or 1; AND<br>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<br>The treatment must not exceed a total of 7 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 13431 |
| | C13432 | | | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing treatment - 3 weekly treatment regimen<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first. | Compliance with Authority Required procedures - Streamlined Authority Code 13432 |
| | C13436 | | | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment - 6 weekly treatment regimen<br>Patient must not have previously been treated for this condition in the metastatic setting; OR<br>The condition must have progressed after treatment with tepotinib; AND<br>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<br>Patient must have a WHO performance status of 0 or 1; AND<br>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 | Compliance with Authority Required procedures - Streamlined Authority Code 13436 |

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| | | | | 1 (ROS1) gene arrangement in tumour material; AND<br>The treatment must not exceed a total of 4 doses under this restriction. | |
| | C13437 | | | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing treatment - 6 weekly treatment regimen<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under both initial and continuing treatment restrictions, whichever comes first. | Compliance with Authority Required procedures - Streamlined Authority Code 13437 |
| | C13726 | | | Relapsed or Refractory Hodgkin lymphoma<br>Initial treatment<br>Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; OR<br>Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition; AND<br>Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | Compliance with Authority Required procedures - Streamlined Authority Code 13726 |
| | C13727 | | | Relapsed or refractory primary mediastinal B-cell lymphoma<br>Initial treatment<br>The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan; AND<br>Patient must have been treated with rituximab-based chemotherapy for this condition; AND<br>Patient must be experiencing relapsed/refractory disease; AND<br>Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of | Compliance with Authority Required procedures - Streamlined Authority Code 13727 |

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| | | | | treatment; OR<br>Patient must have undergone an autologous stem cell transplant (ASCT); OR<br>Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy; AND<br>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<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | |
| | C13728 | | | Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer<br>Initial treatment<br>Patient must be untreated for this PBS indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease); AND<br>Patient must not have received prior treatment for colorectal cancer with each of: (i) a programmed cell death-1 (PD-1) inhibitor, (ii) a programmed cell death ligand-1 (PD-L1) inhibitor; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | Compliance with Authority Required procedures |
| | C13730 | | | Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |

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| | | | | Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND<br>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime. | |
| | C13731 | | | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND<br>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime. | Compliance with Authority Required procedures - Streamlined Authority Code 13731 |
| | C13732 | | | Relapsed or refractory primary mediastinal B-cell lymphoma<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND<br>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is | Compliance with Authority Required procedures - Streamlined Authority Code 13732 |

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| | | | | extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime. | |
| | C13735 | | | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx<br>Initial treatment<br>The condition must be incurable by local therapies in the locally advanced setting; AND<br>Patient must not have had systemic therapy for this condition in the recurrent or metastatic setting prior to initiating PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if previously treated in the locally advanced setting; AND<br>Patient must have had a WHO performance status of 0 or 1; AND<br>The treatment must be either: (i) the sole PBS-subsidised therapy where the condition expresses programmed cell death ligand 1 (PD-L1) with a combined positive score (CPS) greater than or equal to 20 in the tumour sample, (ii) in combination with platinum-based chemotherapy, unless contraindicated or not tolerated.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | Compliance with Authority Required procedures - Streamlined Authority Code 13735 |
| | C13736 | | | Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND<br>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a | Compliance with Authority Required procedures - Streamlined Authority Code 13736 |

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| | | | | lifetime. | |
| | C13738 | | | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx<br>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements<br>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 October 2022; AND<br>Patient must not have had systemic therapy for this condition in the recurrent or metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if treated in the locally advanced setting prior to non-PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must have been initiated as non-PBS-subsidised therapy as either: (i) the sole therapy where the condition expressed programmed cell death ligand 1 (PD-L1) with a combined positive score (CPS) greater than or equal to 20 in the tumour sample, (ii) in combination with platinum-based chemotherapy, unless contraindicated or not tolerated; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND<br>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime. | Compliance with Authority Required procedures - Streamlined Authority Code 13738 |
| | C13739 | | | Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The condition must have progressed on or after prior platinum based chemotherapy; OR<br>The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; | Compliance with Authority Required procedures - Streamlined Authority Code 13739 |

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| | | | | OR<br>The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>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.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | |
| | C13741 | | | Relapsed or Refractory Hodgkin lymphoma<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND<br>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime. | Compliance with Authority Required procedures - Streamlined Authority Code 13741 |
| | C13948 | | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Initial treatment<br>Patient must have a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records; AND<br>The condition must be untreated; AND | Compliance with Authority Required procedures - Streamlined Authority Code 13948 |

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| | | | | Patient must have a WHO performance status of 2 or less.<br>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR<br>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | |
| | C13949 | | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR<br>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND<br>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime. | Compliance with Authority Required procedures - Streamlined Authority Code 13949 |
| | C13986 | | | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements<br>Patient must be currently receiving non-PBS-subsidised treatment with this drug for this | Compliance with Authority Required procedures - |

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| | | | | condition, with treatment having commenced prior to 1 May 2023; AND<br>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<br>The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment, (v) treatment is occurring with a dosing regimen specified in this drug's approved Australian Product Information, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | Streamlined Authority Code 13986 |
| | C14027 | | | Advanced, metastatic or recurrent endometrial carcinoma<br>Initial treatment<br>Patient must have received prior treatment with platinum-based chemotherapy; AND<br>The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.<br>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR<br>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR | Compliance with Authority Required procedures - Streamlined Authority Code 14027 |

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| | | | | Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | |
| | C14028 | | | Advanced, metastatic or recurrent endometrial carcinoma<br>Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements<br>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND<br>The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (v) disease progression has not occurred whilst on treatment, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose.<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | Compliance with Authority Required procedures - Streamlined Authority Code 14028 |
| | C14044 | | | Advanced, metastatic or recurrent endometrial carcinoma<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.<br>Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR<br>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe | Compliance with Authority Required procedures - Streamlined Authority Code 14044 |

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| | | | | up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND<br>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime. | |
| Perampanel | C4656 | | | Intractable partial epileptic seizures<br>Initial<br>The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.<br>Must be treated by a neurologist. | Compliance with Authority Required procedures - Streamlined Authority Code 4656 |
| | C4658 | P4658 | | Intractable partial epileptic seizures<br>Continuing<br>Patient must have previously been issued with an authority prescription for this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 4658 |
| | C7789 | P7789 | | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition.<br>Patient must be aged 12 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 7789 |
| | C7815 | | | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures<br>Initial treatment<br>Must be treated by a neurologist.<br>The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs; | Compliance with Authority Required procedures - Streamlined Authority Code 7815 |

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| | | | | AND<br>The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug; AND<br>The treatment must be for dose titration purposes.<br>Patient must be aged 12 years or older. | |
| Perfluorohexyloctane | C6172 | | | Severe dry eye syndrome<br>Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 6172 |
| Perhexiline | C5592 | | | Angina<br>The condition must not be responding to other therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5592 |
| Perindopril with amlodipine | C4398 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>The condition must be inadequately controlled with an ACE inhibitor; OR<br>The condition must be inadequately controlled with a dihydropyridine calcium channel blocker. | |
| | C4418 | | | Stable coronary heart disease<br>The treatment must not be for the initiation of therapy for coronary heart disease; AND<br>The condition must be stabilised by treatment with perindopril and amlodipine at the same doses. | |
| Perindopril with indapamide | C4375 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>The condition must be inadequately controlled with an ACE inhibitor; OR<br>The condition must be inadequately controlled with a thiazide-like diuretic. | |
| Pertuzumab | C10414 | | | Metastatic (Stage IV) HER2 positive breast cancer<br>Continuing treatment | Compliance with Authority Required |

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| | | | | Patient must have previously been issued with an authority prescription for this drug for this condition; AND<br>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND<br>The treatment must be in combination with trastuzumab; AND<br>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.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>The treatment must not exceed a lifetime total of one course. However, treatment breaks are permitted. A patient who has a treatment break in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug.<br>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. | procedures |
| | C13018 | | | Metastatic (Stage IV) HER2 positive breast cancer<br>Initial treatment<br>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<br>Patient must have a WHO performance status of 0 or 1; AND<br>Patient must not have received prior anti-HER2 therapy for this condition; AND<br>Patient must not have received prior chemotherapy for this condition; AND<br>The treatment must be in combination with trastuzumab and a taxane; AND<br>The treatment must not be in combination with nab-paclitaxel; AND<br>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.<br>Details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) must be provided at the time of application. | Compliance with Authority Required procedures |

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| | | | | The pathology report must be documented in the patient's medical records.<br>Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. | |
| Phenelzine | C6236 | | | Depression<br>The treatment must be for when all other anti-depressant therapy has failed; OR<br>The treatment must be for when all other anti-depressant therapy is inappropriate. | |
| Phenobarbital | C6295 | | | Epilepsy | |
| Phenoxybenzamine | C6145 | | | Phaeochromocytoma | |
| | C6178 | | | Neurogenic urinary retention | |
| Phenoxymethylpenicillin | | P5697 | | Recurrent streptococcal infections (including rheumatic fever)<br>The treatment must be for prophylaxis. | |
| Phenylalanine with carbohydrate | C5533 | | | Tyrosinaemia | |
| Pimecrolimus | C5472 | | | Atopic dermatitis<br>Short-term (up to 3 weeks) intermittent treatment<br>Patient must be at least 3 months of age.<br>The condition must be on the patient's face; OR<br>The condition must be on the patient's eyelid; AND<br>Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy; AND<br>The condition must have been initially diagnosed more than three months prior to this treatment; AND<br>Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.<br>Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:<br>(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or | Compliance with Authority Required procedures - Streamlined Authority Code 5472 |

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| | | | | (ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or<br>(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or<br>(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions | |
| | C5482 | | | Atopic dermatitis<br>Patient must be at least 3 months of age.<br>The condition must be on the patient's face; OR<br>The condition must be on the patient's eyelid; AND<br>Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure; AND<br>Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period. | Compliance with Authority Required procedures - Streamlined Authority Code 5482 |
| Pioglitazone | C4363 | | | Diabetes mellitus type 2<br>The treatment must be in combination with metformin; OR<br>The treatment must be in combination with a sulfonylurea; AND<br>Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR<br>Patient must not have tolerated a combination of metformin and a sulfonylurea; AND<br>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR<br>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea. | Compliance with Authority Required procedures - Streamlined Authority Code 4363 |

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| | | | | The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | |
| | C4364 | | | Diabetes mellitus type 2<br>The treatment must be in combination with metformin; AND<br>The treatment must be in combination with a sulfonylurea; AND<br>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR<br>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.<br>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and | Compliance with Authority Required procedures - Streamlined Authority Code 4364 |

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| | | | | haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | |
| | C4388 | | | Diabetes mellitus type 2<br>The treatment must be in combination with insulin; AND<br>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR<br>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.<br>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.<br>The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.<br>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:<br>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or<br>(b) Had red cell transfusion within the previous 3 months.<br>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 4388 |
| Pirfenidone | C13378 | | | Idiopathic pulmonary fibrosis<br>Initial treatment 1 - new patient | Compliance with Written Authority Required |

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| | | | | The condition must be diagnosed through a multidisciplinary team; AND<br>Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months; AND<br>Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height; AND<br>Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7; AND<br>Patient must not have had an acute respiratory infection at the time of FVC measurement; AND<br>Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%; AND<br>Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND<br>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement.<br>A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.<br>Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.<br>Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. | procedures |

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| | | | | If the application is submitted through HPOS form upload or mail, it must include:<br>(a) a completed authority prescription form; and<br>(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) | |
| | C13380 | | | Idiopathic pulmonary fibrosis<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND<br>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| | C13381 | | | Idiopathic pulmonary fibrosis<br>Initial treatment 2 - change or recommencement of treatment<br>Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Must be treated by a medical practitioner who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) in consultation with a respiratory physician or specialist physician; AND<br>Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis; AND<br>Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. | Compliance with Authority Required procedures |
| Piroxicam | C6214 | | | Chronic arthropathies (including osteoarthritis)<br>The condition must have an inflammatory component. | |

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| Plerixafor | C4549 | | | Mobilisation of haematopoietic stem cells<br>The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND<br>Patient must have lymphoma; OR<br>Patient must have multiple myeloma; AND<br>Patient must require autologous stem cell transplantation; AND<br>Patient must have failed previous stem cell collection; OR<br>Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR<br>Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.<br>Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 4549 |
| | C9329 | | | Mobilisation of haematopoietic stem cells<br>The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND<br>Patient must have lymphoma; OR<br>Patient must have multiple myeloma; AND<br>Patient must require autologous stem cell transplantation; AND<br>Patient must have failed previous stem cell collection; OR<br>Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR<br>Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.<br>Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9329 |
| Polyethylene glycol 400 with propylene glycol | C6073 | P6073 | | Severe dry eye syndrome, including Sjogren's syndrome | |
| | C6098 | P6098 | | Severe dry eye syndrome, including Sjogren's syndrome<br>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 | |

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| | | | | the Arrangements. | |
| | C6120 | | | Severe dry eye syndrome, including Sjogren's syndrome | |
| | C6172 | | | Severe dry eye syndrome<br>Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 6172 |
| Poly-l-lactic acid | C5087 | P5087 | | Severe facial lipoatrophy<br>Initial PBS-subsidised treatment<br>The treatment must be for facial administration only; AND<br>The condition must be caused by therapy for HIV infection.<br>Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector. | Compliance with Authority Required procedures |
| | C5122 | P5122 | | Severe facial lipoatrophy<br>Maintenance PBS-subsidised treatment<br>The treatment must be for facial administration only; AND<br>The condition must be caused by therapy for HIV infection.<br>Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector. | Compliance with Authority Required procedures |
| Polyvinyl alcohol | C6073 | P6073 | | Severe dry eye syndrome, including Sjogren's syndrome | |
| | C6098 | P6098 | | Severe dry eye syndrome, including Sjogren's syndrome<br>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. | |
| | C6120 | | | Severe dry eye syndrome, including Sjogren's syndrome | |

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| Ponatinib | C5572 | P5572 | | Acute lymphoblastic leukaemia<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must be expressing the T315I mutation; AND<br>Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor; AND<br>Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).<br>Failure of treatment is defined as either:<br>1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;<br>2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;<br>3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.<br>Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.<br>The authority application must be made in writing and must include:<br>1. a completed authority prescription form; and<br>2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and<br>3. a signed patient acknowledgement; and<br>4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided | Compliance with Written Authority Required procedures |
| | C5589 | P5589 | | Acute lymphoblastic leukaemia<br>Continuing treatment<br>Patient must have previously been issued with an authority prescription for this drug for this condition; AND | Compliance with Authority Required procedures |

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| | | | | The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have progressive disease. | |
| | C9465 | P9465 | | Acute lymphoblastic leukaemia<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| | C9614 | P9614 | | Acute lymphoblastic leukaemia<br>Initial treatment<br>The condition must be expressing the Philadelphia chromosome; OR<br>The condition must have the transcript BCR-ABL; AND<br>Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; OR<br>Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal.<br>Failure of treatment with dasatinib is defined as either:<br>1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or<br>2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or<br>3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.<br>Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.<br>The authority application must be made in writing and must include:<br>1. a completed authority prescription form; and<br>2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting | Compliance with Written Authority Required procedures |

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| | | | | Information Form; and<br>3. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided; or<br>4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided | |
| | C13006 | P13006 | | Chronic Myeloid Leukaemia (CML)<br>Subsequent continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have maintained a major cytogenic response of less than 35% Philadelphia positive bone marrow cells at 12 month intervals; OR<br>Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% on the international scale at 12 month intervals.<br>A pathology report demonstrating the patient's cytogenetic response or a peripheral blood level of BCR-ABL must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| | C13022 | P13022 | | Chronic Myeloid Leukaemia (CML)<br>First continuing treatment<br>Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR<br>Patient must demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals.<br>The first continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:<br>(i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note | Compliance with Written Authority Required procedures |

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| | | | | explaining definitions of response]; or<br>(ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].<br>All reports must be documented in the patient's medical records.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(i) A completed authority prescription form; and<br>(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). | |
| | C13025 | P13025 | | Chronic Myeloid Leukaemia (CML)<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR<br>Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal; AND<br>Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority; OR<br>Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR<br>Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.<br>Failure of an adequate trial of dasatinib or nilotinib is defined as:<br>1. Lack of response to dasatinib or nilotinib therapy, defined as either:<br>(i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or<br>(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or<br>(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR<br>2. Loss of a previously documented major cytogenetic response (demonstrated by the presence | Compliance with Written Authority Required procedures |

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| | | | | of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR<br>3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR<br>4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR<br>5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>Accelerated phase is defined by the presence of 1 or more of the following:<br>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>3. Peripheral basophils greater than or equal to 20%; or<br>4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).<br>Blast crisis is defined as either:<br>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>2. Extramedullary involvement other than spleen and liver.<br>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:<br>(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or<br>(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and<br>(iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique | |

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| | | | | identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.<br>All reports must be documented in the patient's medical records<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(i) A completed authority prescription form; and<br>(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).<br>Up to a maximum of 18 months of treatment may be authorised under this initial restriction. | |
| | C13030 | P13030 | | Chronic Myeloid Leukaemia (CML)<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report; AND<br>Patient must have failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority; OR<br>Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR<br>Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority.<br>Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:<br>1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:<br>(i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or<br>(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or<br>(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR<br>2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR | Compliance with Written Authority Required procedures |

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| | | | | 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR<br>4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR<br>5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>Accelerated phase is defined by the presence of 1 or more of the following:<br>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>3. Peripheral basophils greater than or equal to 20%; or<br>4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).<br>Blast crisis is defined as either:<br>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>2. Extramedullary involvement other than spleen and liver.<br>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:<br>(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or<br>(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and<br>(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and | |

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| | | | | (iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.<br>All reports must be documented in the patient's medical records.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(i) A completed authority prescription form; and<br>(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).<br>Up to a maximum of 18 months of treatment may be authorised under this initial restriction. | |
| Posaconazole | C5169 | | | Fungal infection<br>The condition must be fusariosis; OR<br>The condition must be zygomycosis; OR<br>The condition must be coccidioidomycosis; OR<br>The condition must be chromoblastomycosis; OR<br>The condition must be mycetoma; AND<br>Patient must be unable to tolerate alternative therapy; OR<br>Patient must have disease refractory to alternative therapy. | Compliance with Authority Required procedures |
| | C5395 | | | Invasive aspergillosis<br>Patient must be unable to tolerate alternative therapy; OR<br>Patient must have disease refractory to alternative therapy. | Compliance with Authority Required procedures |
| | C5396 | | | Prophylaxis of invasive fungal infections including both yeasts and moulds<br>Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR<br>Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.<br>Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 | Compliance with Authority Required procedures |

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| | | | | cells per cubic millimetre.<br>Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.<br>No more than 6 months therapy per episode will be PBS-subsidised | |
| Pralatrexate | C7526 | | | Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma<br>Continuing treatment<br>The condition must be relapsed or chemotherapy refractory; AND<br>Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| | C7558 | | | Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma<br>Initial treatment<br>The condition must be relapsed or chemotherapy refractory; AND<br>Patient must have undergone appropriate prior front-line curative intent chemotherapy. | Compliance with Authority Required procedures |
| Pramipexole | C5131 | | | Parkinson disease | |
| | C5363 | P5363 | | Parkinson disease | |
| | C5411 | P5411 | | Primary severe restless legs syndrome<br>Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome; AND<br>Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.<br>The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.<br>The diagnostic criteria for Restless Legs Syndrome are:<br>(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and<br>(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and<br>(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and | |

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| | | | | (d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night. | |
| Pravastatin | | P7598 | | For use in patients who are 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. | |
| Praziquantel | C5659 | | | Schistosomiasis | Compliance with Authority Required procedures - Streamlined Authority Code 5659 |
| Prednisolone | C4872 | | | Ulcerative colitis | |
| | C4893 | | | Proctitis | |
| | C6087 | | | Uveitis | |
| | C6101 | P6101 | | Uveitis | |
| | C10095 | P10095 | | Severe eye inflammation<br>Patient must have had a cataract removed in the treated eye; OR<br>Patient must be scheduled for cataract surgery in the treated eye.<br>Patient must identify as Aboriginal or Torres Strait Islander. | |
| Prednisolone with phenylephrine | C6080 | P6080 | | Corneal grafts | |
| | C6087 | | | Uveitis | |
| | C6101 | P6101 | | Uveitis | |
| | C10095 | P10095 | | Severe eye inflammation<br>Patient must have had a cataract removed in the treated eye; OR<br>Patient must be scheduled for cataract surgery in the treated eye.<br>Patient must identify as Aboriginal or Torres Strait Islander. | |

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| Pregabalin | C4172 | | | Neuropathic pain<br>The condition must be refractory to treatment with other drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 4172 |
| Progesterone | C4997 | | | Assisted Reproductive Technology<br>The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women; AND<br>Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.<br>The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement. | Compliance with Authority Required procedures - Streamlined Authority Code 4997 |
| | C5045 | | | Assisted Reproductive Technology<br>The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women; AND<br>Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.<br>The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement. | Compliance with Authority Required procedures - Streamlined Authority Code 5045 |
| | C11673 | | | Prevention of preterm birth<br>Patient must have a singleton pregnancy; AND<br>Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth; AND<br>The treatment must be administered no earlier than at 16 weeks gestation. | Compliance with Authority Required procedures - Streamlined Authority Code 11673 |
| | C11835 | | | Prevention of preterm birth<br>Patient must have a singleton pregnancy; AND<br>Patient must have at least one of: (i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth; AND<br>The treatment must be administered no earlier than at 16 weeks gestation. | Compliance with Authority Required procedures - Streamlined Authority Code 11835 |

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| Propantheline | C6241 | | | Detrusor overactivity | |
| Protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid | C5970 | | | Phenylketonuria | |
| Protein formula with carbohydrate, fat, vitamins and minerals | C6890 | | | Dietary management of conditions requiring a source of medium chain triglycerides<br>Patient must have fat malabsorption due to liver disease; OR<br>Patient must have fat malabsorption due to short gut syndrome; OR<br>Patient must have fat malabsorption due to cystic fibrosis; OR<br>Patient must have fat malabsorption due to gastrointestinal disorders.<br>Patient must be aged from 1 to 10 years inclusive. | |
| Protein formula with vitamins and minerals, and low in potassium, phosphorus, calcium, chloride and vitamin A | C11070 | | | Chronic renal failure<br>Patient must be a child aged 3 years or older.<br>Patient must require treatment with a low protein and a low phosphorus diet; OR<br>Patient must require treatment with a low protein, low phosphorus and low potassium diet. | Compliance with Authority Required procedures - Streamlined Authority Code 11070 |
| Protein hydrolysate formula with medium chain triglycerides | C6137 | | | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein<br>Initial treatment for up to 6 months<br>Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.<br>Patient must be up to the age of 24 months.<br>The name of the specialist must be documented in the patient's medical records | Compliance with Authority Required procedures - Streamlined Authority Code 6137 |
| | C6138 | | | Severe intestinal malabsorption including short bowel syndrome | Compliance with Authority Required procedures - |

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| | | | | | Streamlined Authority Code 6138 |
| | C6148 | | | Severe diarrhoea of greater than 2 weeks duration<br>Patient must be aged less than 4 months. | Compliance with Authority Required procedures - Streamlined Authority Code 6148 |
| | C6157 | | | Chronic liver failure with fat malabsorption | Compliance with Authority Required procedures - Streamlined Authority Code 6157 |
| | C6158 | | | Enterokinase deficiency | Compliance with Authority Required procedures - Streamlined Authority Code 6158 |
| | C6166 | | | Proven fat malabsorption | Compliance with Authority Required procedures - Streamlined Authority Code 6166 |
| | C6174 | | | Cows' milk protein enteropathy and intolerance to soy protein<br>Initial treatment<br>Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.<br>The condition must not be isolated infant colic or reflux; AND | Compliance with Authority Required procedures - Streamlined Authority Code 6174 |

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| | | | | Patient must have failed to respond to a strict soy-based cows' milk protein free diet.<br>Patient must be up to the age of 24 months. | |
| | C6182 | | | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein<br>Continuing treatment<br>Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.<br>Patient must be up to the age of 24 months.<br>The name of the specialist must be documented in the patient's medical records | Compliance with Authority Required procedures - Streamlined Authority Code 6182 |
| | C6193 | | | Cows' milk protein enteropathy and intolerance to soy protein<br>Continuing treatment<br>Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.<br>The condition must not be isolated infant colic or reflux; AND<br>Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.<br>Patient must be up to the age of 24 months. | Compliance with Authority Required procedures - Streamlined Authority Code 6193 |
| | C6194 | | | Biliary atresia | Compliance with Authority Required procedures - Streamlined Authority Code 6194 |
| | C6195 | | | Cystic fibrosis | Compliance with Authority Required procedures - Streamlined Authority Code 6195 |
| | C6204 | | | Cows' milk protein enteropathy and intolerance to soy protein | Compliance with |

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| | | | | Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.<br>The condition must not be isolated infant colic or reflux; AND<br>Patient must have failed to respond to a strict soy-based cows' milk protein free diet.<br>Patient must be older than 24 months of age.<br>The name of the specialist must be documented in the patient's medical records | Authority Required procedures - Streamlined Authority Code 6204 |
| | C6205 | | | Chylous ascites | Compliance with Authority Required procedures - Streamlined Authority Code 6205 |
| | C6206 | | | Chylothorax | Compliance with Authority Required procedures - Streamlined Authority Code 6206 |
| Quetiapine | C4246 | | | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 4246 |
| | C5611 | | | Acute mania<br>The condition must be associated with bipolar I disorder; AND<br>The treatment must be as monotherapy; AND<br>The treatment must be limited to up to 6 months per episode. | Compliance with Authority Required procedures - Streamlined Authority Code 5611 |
| | C5639 | | | Bipolar I disorder<br>The treatment must be maintenance therapy. | Compliance with Authority Required procedures - |

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| | | | | | Streamlined Authority Code 5639 |
| | C7893 | | | Bipolar I disorder<br>The treatment must be maintenance therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 7893 |
| | C7916 | | | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 7916 |
| | C7927 | | | Acute mania<br>The condition must be associated with bipolar I disorder; AND<br>The treatment must be as monotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 7927 |
| Quinagolide | C5136 | | | Pathological hyperprolactinaemia<br>Patient must be one in whom surgery is not indicated. | |
| | C5137 | | | Pathological hyperprolactinaemia<br>Patient must have had surgery for this condition with incomplete resolution. | |
| | C5357 | | | Pathological hyperprolactinaemia<br>Patient must have had radiotherapy for this condition with incomplete resolution. | |
| | C5398 | | | Pathological hyperprolactinaemia<br>Patient must be one in whom radiotherapy is not indicated. | |
| Quinapril with hydrochlorothiazide | C4389 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND | |

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| | | | | The condition must be inadequately controlled with an ACE inhibitor; OR<br>The condition must be inadequately controlled with a thiazide diuretic. | |
| Quinine | C5633 | | | Malaria | Compliance with Authority Required procedures - Streamlined Authority Code 5633 |
| Rabeprazole | C5444 | | | Gastro-oesophageal reflux disease | |
| | C5512 | | | Scleroderma oesophagus | |
| | C8774 | P8774 | | Gastro-oesophageal reflux disease<br>The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR<br>The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease. | Compliance with Authority Required procedures - Streamlined Authority Code 8774 |
| | C8775 | P8775 | | Peptic ulcer<br>Initial treatment<br>Patient must have tested negative for helicobacter pylori infection; OR<br>Patient must have failed treatment with helicobacter pylori eradication therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 8775 |
| | C8776 | P8776 | | Gastro-oesophageal reflux disease<br>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 8776 |
| | C8780 | P8780 | | Scleroderma oesophagus | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 8780 |
| | C11310 | P11310 | | Complex gastro-oesophageal reflux disease (GORD)<br>One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control<br>Must be treated by a gastroenterologist; OR<br>Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR<br>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<br>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.<br>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<br>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<br>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<br>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<br>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.<br>Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction. | Compliance with Authority Required procedures |
| Raloxifene | C6314 | | | Established post-menopausal osteoporosis<br>Patient must have fracture due to minimal trauma; AND<br>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive | Compliance with Authority Required procedures - |

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| | | | | agent for this condition.<br>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.<br>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Streamlined Authority Code 6314 |
| Raltegravir | C4274 | | | HIV infection<br>Continuing<br>The treatment must be in combination with other antiretroviral agents; AND<br>Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND<br>Patient must have previously received PBS-subsidised therapy for HIV infection.<br>Patient must be aged 2 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4274 |
| | C4275 | | | HIV infection<br>Initial<br>The treatment must be in combination with other antiretroviral agents; AND<br>Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND<br>Patient must have a CD4 count of less than 500 per cubic millimetre; OR<br>Patient must have symptomatic HIV disease.<br>Patient must be aged 2 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4275 |
| | C4454 | | | HIV infection<br>Continuing<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| | C4512 | | | HIV infection<br>Initial | Compliance with Authority Required |

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| | | | | Patient must be antiretroviral treatment naive; AND<br>The treatment must be in combination with other antiretroviral agents. | procedures - Streamlined Authority Code 4512 |
| Ramipril with felodipine | C4398 | | | Hypertension<br>The treatment must not be for the initiation of anti-hypertensive therapy; AND<br>The condition must be inadequately controlled with an ACE inhibitor; OR<br>The condition must be inadequately controlled with a dihydropyridine calcium channel blocker. | |
| Ranibizumab | C13336 | P13336 | | Central retinal vein occlusion with macular oedema<br>Continuing treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13336 |
| | C13337 | P13337 | | Subfoveal choroidal neovascularisation (CNV)<br>Initial treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must be due to pathologic myopia (PM); AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Authority approval for initial treatment of each eye must be sought.<br>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) A completed authority prescription form; and<br>(b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Written Authority Required procedures |

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| | | | | All reports must be documented in the patient's medical records. | |
| | C13340 | P13340 | | Subfoveal choroidal neovascularisation (CNV)<br>Continuing treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must not be due to pathologic myopia; AND<br>The condition must not be due to age-related macular degeneration; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye. | Compliance with Authority Required procedures - Streamlined Authority Code 13340 |
| | C13384 | P13384 | | Branch retinal vein occlusion with macular oedema<br>Initial treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO); AND<br>Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment; AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Authority approval for initial treatment of each eye must be sought.<br>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) A completed authority prescription form; and<br>(b) A completed authority application form relevant to the indication and treatment phase (the | Compliance with Written Authority Required procedures |

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| | | | | latest version is located on the website specified in the Administrative Advice).<br>All reports must be documented in the patient's medical records. | |
| | C13387 | P13387 | | Branch retinal vein occlusion with macular oedema<br>Continuing treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13387 |
| | C13388 | P13388 | | Diabetic macular oedema (DMO)<br>Initial treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>Patient must have visual impairment due to diabetic macular oedema; AND<br>Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment; AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>The treatment must be as monotherapy; OR<br>The treatment must be in combination with laser photocoagulation; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Authority approval for initial treatment of each eye must be sought.<br>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) A completed authority prescription form; and<br>(b) A completed authority application form relevant to the indication and treatment phase (the | Compliance with Written Authority Required procedures |

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| | | | | latest version is located on the website specified in the Administrative Advice).<br>All reports must be documented in the patient's medical records. | |
| | C13390 | P13390 | | Central retinal vein occlusion with macular oedema<br>Initial treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO); AND<br>Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment; AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Authority approval for initial treatment of each eye must be sought.<br>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) A completed authority prescription form; and<br>(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).<br>All reports must be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| | C13392 | P13392 | | Subfoveal choroidal neovascularisation (CNV)<br>Continuing treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must be due to pathologic myopia (PM); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 13392 |

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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye. | |
| | C13402 | P13402 | | Diabetic macular oedema (DMO)<br>Continuing treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye; AND<br>The treatment must be as monotherapy; OR<br>The treatment must be in combination with laser photocoagulation; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 13402 |
| | C13406 | P13406 | | Subfoveal choroidal neovascularisation (CNV)<br>Continuing treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must be due to age-related macular degeneration (AMD); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye. | Compliance with Authority Required procedures - Streamlined Authority Code 13406 |
| | C13422 | P13422 | | Subfoveal choroidal neovascularisation (CNV)<br>Initial treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must be due to age-related macular degeneration (AMD); AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Authority approval for initial treatment of each eye must be sought.<br>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) Details (date, unique identifying number/code or provider number) of the optical coherence | Compliance with Written Authority Required procedures |

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| | | | | tomography or fluorescein angiogram report.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) A completed authority prescription form; and<br>(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).<br>All reports must be documented in the patient's medical records. | |
| | C13427 | P13427 | | Subfoveal choroidal neovascularisation (CNV)<br>Initial treatment<br>Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.<br>The condition must not be due to pathologic myopia; AND<br>The condition must not be due to age-related macular degeneration; AND<br>The condition must be diagnosed by optical coherence tomography; OR<br>The condition must be diagnosed by fluorescein angiography; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Authority approval for initial treatment of each eye must be sought.<br>The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:<br>(1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) A completed authority prescription form; and<br>(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).<br>All reports must be documented in the patient's medical records. | Compliance with Written Authority Required procedures |
| Rasagiline | C5339 | | | Parkinson disease | |
| Reboxetine | C5650 | | | Major depressive disorders | |
| Ribavirin | C5957 | | | Chronic hepatitis C infection<br>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND | Compliance with Authority Required |

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| | | | | Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND<br>The treatment must be limited to a maximum duration of 12 weeks.<br>Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. | procedures |
| Ribociclib | C13037 | P13037 | | Locally advanced or metastatic breast cancer<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND<br>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND<br>Patient must require dosage reduction requiring a pack of 42 tablets.<br>Patient must not be premenopausal. | Compliance with Authority Required procedures |
| | C13074 | P13074 | | Locally advanced or metastatic breast cancer<br>Initial treatment<br>Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR<br>Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND<br>The condition must be hormone receptor positive; AND<br>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND<br>The condition must be inoperable; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND<br>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) | Compliance with Authority Required procedures |

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| | | | | fulvestrant; OR<br>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<br>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND<br>Patient must require dosage reduction requiring a pack of 42 tablets.<br>Patient must not be premenopausal. | |
| | C13084 | P13084 | | Locally advanced or metastatic breast cancer<br>Initial treatment<br>Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR<br>Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND<br>The condition must be hormone receptor positive; AND<br>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND<br>The condition must be inoperable; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND<br>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<br>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<br>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.<br>Patient must not be premenopausal. | Compliance with Authority Required procedures |
| | C13093 | P13093 | | Locally advanced or metastatic breast cancer<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures |

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| | | | | Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND<br>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.<br>Patient must not be premenopausal. | |
| | C13099 | P13099 | | Locally advanced or metastatic breast cancer<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant; AND<br>Patient must require dosage reduction requiring a pack of 21 tablets; AND<br>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.<br>Patient must not be premenopausal. | Compliance with Authority Required procedures |
| | C13105 | P13105 | | Locally advanced or metastatic breast cancer<br>Initial treatment<br>Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR<br>Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND<br>The condition must be hormone receptor positive; AND<br>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND<br>The condition must be inoperable; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND<br>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) | Compliance with Authority Required procedures |

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| | | | | fulvestrant; OR<br>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<br>The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; AND<br>Patient must require dosage reduction requiring a pack of 21 tablets.<br>Patient must not be premenopausal. | |
| Rifabutin | C6350 | | | Mycobacterium avium complex infection<br>Patient must be human immunodeficiency virus (HIV) positive. | Compliance with Authority Required procedures - Streamlined Authority Code 6350 |
| | C6356 | | | Mycobacterium avium complex infection<br>The treatment must be for prophylaxis; AND<br>Patient must be human immunodeficiency virus (HIV) positive; AND<br>Patient must have CD4 cell counts of less than 75 per cubic millimetre. | Compliance with Authority Required procedures - Streamlined Authority Code 6356 |
| | C9560 | | | Mycobacterium avium complex infection<br>Patient must be human immunodeficiency virus (HIV) positive. | Compliance with Authority Required procedures - Streamlined Authority Code 9560 |
| | C9622 | | | Mycobacterium avium complex infection<br>The treatment must be for prophylaxis; AND<br>Patient must be human immunodeficiency virus (HIV) positive; AND<br>Patient must have CD4 cell counts of less than 75 per cubic millimetre. | Compliance with Authority Required procedures - Streamlined Authority Code 9622 |

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| Rifampicin | C5536 | P5536 | | Meningococcal disease<br>The treatment must be for prophylaxis; AND<br>Patient must be a carrier of the disease; OR<br>Patient must be in close contact with people who have the disease. | |
| | C5552 | P5552 | | Leprosy<br>Patient must be an adult. | Compliance with Authority Required procedures |
| | C5585 | P5585 | | Haemophilus influenzae type B<br>The treatment must be for prophylaxis; AND<br>Patient must be in contact with people who have the disease. | |
| | C11018 | P11018 | | Mycobacterium ulcerans infection (Buruli ulcer)<br>The treatment must be used in combination with another antibiotic for the treatment of Buruli ulcer. | Compliance with Authority Required procedures |
| Rifaximin | C4306 | | | Prevention of hepatic encephalopathy<br>Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.<br>The treatment must be in combination with lactulose, if lactulose is tolerated; AND<br>Patient must have had prior episodes of hepatic encephalopathy. | Compliance with Authority Required procedures |
| Rilpivirine | C4454 | | | HIV infection<br>Continuing<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| | C4512 | | | HIV infection<br>Initial<br>Patient must be antiretroviral treatment naive; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4512 |

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| Riluzole | C5341 | | | Amyotrophic lateral sclerosis<br>Initial treatment<br>The condition must be diagnosed by a neurologist; AND<br>Patient must not have had the disease for more than 5 years; AND<br>Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug; AND<br>Patient must be ambulatory; OR<br>Patient must not be ambulatory, and must be able to either use upper limbs or to swallow; AND<br>Patient must not have undergone a tracheostomy; AND<br>Patient must not have experienced respiratory failure.<br>The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application. | Compliance with Authority Required procedures |
| | C8738 | | | Amyotrophic lateral sclerosis<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must be ambulatory; OR<br>Patient must not be ambulatory, and must be able to either use upper limbs or to swallow; AND<br>Patient must not have undergone a tracheostomy; AND<br>Patient must not have experienced respiratory failure. | Compliance with Authority Required procedures |
| Ripretinib | C12440 | | | Metastatic or unresectable malignant gastrointestinal stromal tumour<br>Initial treatment<br>The condition must not be resectable; AND<br>The treatment must be as monotherapy; AND<br>The condition must have progressed despite treatment with all drugs PBS-listed specifically for this PBS-indication; OR<br>The condition must have progressed despite each of: (i) treatment with a drug PBS-listed specifically listed for this PBS-indication, (ii) an intolerance/expected intolerance to all other drugs PBS-listed for this specific PBS-indication; AND<br>Patient must have a WHO performance status of 2 or less.<br>Patient must be undergoing PBS-subsidised treatment with this drug for the first time - | Compliance with Authority Required procedures |

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| | | | | retreatment/continuing treatment beyond the available repeat prescription is not permitted under this listing; see 'Continuing treatment' Treatment Phase listing to continue PBS-subsidised treatment in a patient without disease progression. | |
| | C12455 | | | Metastatic or unresectable malignant gastrointestinal stromal tumour<br>Continuing treatment<br>The condition must not be resectable; AND<br>Patient must have received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be as monotherapy; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures |
| Risankizumab | C6696 | P6696 | | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply<br>Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR<br>Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND<br>The treatment must be as systemic monotherapy (other than methotrexate).<br>Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| | C9933 | P9933 | | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body<br>Must be treated by a dermatologist.<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as:<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is | Compliance with Written Authority Required procedures |

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| | | | | sustained at this level, when compared with the baseline value for this treatment cycle.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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.<br>The most recent PASI assessment must be no more than 1 month old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.<br>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.<br>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.<br>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. | |
| | C9955 | P9955 | | Severe chronic plaque psoriasis<br>Continuing treatment, Face, hand, foot<br>Must be treated by a dermatologist.<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older. | Compliance with Written Authority Required procedures |

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| | | | | An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:<br>(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<br>(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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(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.<br>The most recent PASI assessment must be no more than 1 month old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.<br>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.<br>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.<br>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. | |

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| | C10802 | P10802 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.<br>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.<br>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.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |

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| | C10853 | P10853 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.<br>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.<br>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 | Compliance with Written Authority Required procedures |

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| | | | | a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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. | |
| | C11093 | P11093 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body (new patient)<br>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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 5 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; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>Where treatment with methotrexate, ciclosporin, apremilast 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.<br>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast 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.<br>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, 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.<br>The following criterion indicates failure to achieve an adequate response to prior treatment and | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | must be demonstrated in the patient at the time of the application:<br>(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.<br>(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.<br>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(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<br>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].<br>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.<br>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.<br>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.<br>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. | |

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| | C11120 | P11120 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>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<br>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<br>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<br>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<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.<br>Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| | C11124 | P11124 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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 | Compliance with Written Authority Required procedures |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as:<br>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.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>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.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>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. | |

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| | | | | 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.<br>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. | |
| | C11125 | P11125 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Face, hand, foot (new patient)<br>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<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>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 5 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; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>Where treatment with methotrexate, ciclosporin, apremilast 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.<br>Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast 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.<br>Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, acitretin or phototherapy, the patient is still required to trial 2 of these prior | Compliance with Written Authority Required procedures |

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| | | | | therapies until a failure to achieve an adequate response is met.<br>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:<br>(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:<br>(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<br>(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;<br>(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.<br>(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].<br>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.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>Where a response assessment is not conducted within the required timeframe, the patient will be | |

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| | | | | 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.<br>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.<br>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. | |
| | C11171 | P11171 | | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>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<br>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<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction.<br>Patient must be aged 18 years or older.<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:<br>(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<br>(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.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the | Compliance with Written Authority Required procedures |

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| | | | | timeframes specified below.<br>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.<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>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.<br>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.<br>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. | |
| | C13063 | P13063 | | Severe chronic plaque psoriasis<br>'Grandfathered' patient - Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) | Compliance with Written Authority Required procedures |

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| | | | | Must be treated by a dermatologist.<br>Patient must have severe chronic plaque psoriasis where lesions had been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS-subsidised treatment; AND<br>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2022; AND<br>Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug for this condition; AND<br>Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be at least 18 years of age.<br>An adequate response to treatment is defined as:<br>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.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(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<br>(c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application. | |
| | C13070 | P13070 | | Severe chronic plaque psoriasis<br>Grandfathered patient - Face, hand, foot or Whole body - Balance of Supply<br>Must be treated by a dermatologist.<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Whole body restriction to complete 24 weeks treatment; OR<br>Patient must have received insufficient therapy with this drug for this condition under the Grandfathered patient - Face, hand, foot restriction to complete 24 weeks treatment; AND | Compliance with Authority Required procedures |

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| | | | | The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. | |
| | C13098 | P13098 | | Severe chronic plaque psoriasis<br>'Grandfathered' patient - Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)<br>Must be treated by a dermatologist.<br>Patient must have 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 from the time of initial diagnosis prior to initiating non-PBS-subsidised treatment; AND<br>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2022; AND<br>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<br>Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be at least 18 years of age.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:<br>(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<br>(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.<br>The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and | Compliance with Written Authority Required procedures |

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| | | | | (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 demonstrating response and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and<br>(c) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria. | |
| Risedronic acid | C4877 | | | Symptomatic Paget disease of bone | |
| | C6310 | | | Osteoporosis<br>Patient must be aged 70 years or older.<br>Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND<br>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.<br>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. | |
| | C6323 | | | Corticosteroid-induced osteoporosis<br>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<br>Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND<br>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.<br>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. | |
| | C6327 | | | Established osteoporosis<br>Patient must have fracture due to minimal trauma; AND<br>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive | |

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| | | | | agent for this condition.<br>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.<br>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | |
| Risperidone | C4246 | P4246 | | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 4246 |
| | C5903 | P5903 | | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 5903 |
| | C5907 | P5907 | | Acute mania<br>The condition must be associated with bipolar I disorder; AND<br>The treatment must be as adjunctive therapy to mood stabilisers; AND<br>The treatment must be limited to up to 6 months per episode. | Compliance with Authority Required procedures - Streamlined Authority Code 5907 |
| | C5912 | | | Bipolar I disorder<br>The condition must be refractory to treatment; AND<br>The treatment must be in combination with lithium or sodium valproate; AND<br>The treatment must be maintenance therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5912 |
| | C6897 | P6897 | | Severe behavioural disturbances | Compliance with |

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| | | | | Patient must have autism spectrum disorder; AND<br>The treatment must be under the supervision of a paediatrician or psychiatrist; AND<br>The treatment must be in combination with non-pharmacological measures.<br>Patient must be under 18 years of age.<br>Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.<br>The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders. | Authority Required procedures - Streamlined Authority Code 6897 |
| | C6898 | P6898 | | Severe behavioural disturbances<br>Patient must have autism spectrum disorder; AND<br>The treatment must be under the supervision of a paediatrician or psychiatrist; AND<br>The treatment must be in combination with non-pharmacological measures.<br>Patient must be under 18 years of age.<br>Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.<br>The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders. | Compliance with Authority Required procedures - Streamlined Authority Code 6898 |
| | C6899 | P6899 | | Severe behavioural disturbances<br>Continuing treatment<br>Patient must have autism spectrum disorder; AND<br>Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age; AND<br>The treatment must be under the supervision of a paediatrician or psychiatrist; AND<br>The treatment must be in combination with non-pharmacological measures.<br>Patient must be aged 18 years or older.<br>Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.<br>The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental | Compliance with Authority Required procedures - Streamlined Authority Code 6899 |

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| | | | | and behavioural disorders. | |
| | C6938 | P6938 | | Severe behavioural disturbances<br>Continuing treatment<br>Patient must have autism spectrum disorder; AND<br>Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age; AND<br>The treatment must be under the supervision of a paediatrician or psychiatrist; AND<br>The treatment must be in combination with non-pharmacological measures.<br>Patient must be aged 18 years or older.<br>Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.<br>The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders. | Compliance with Authority Required procedures - Streamlined Authority Code 6938 |
| | C10020 | P10020 | | Behavioural disturbances<br>Initial treatment<br>The condition must be characterised by psychotic symptoms and aggression; AND<br>Patient must have dementia of the Alzheimer type; AND<br>Patient must have failed to respond to non-pharmacological methods of treatment; AND<br>Patient must not receive more than 12 weeks of treatment under this restriction.<br>A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period. | Compliance with Authority Required procedures - Streamlined Authority Code 10020 |
| | C10021 | P10021 | | Behavioural disturbances<br>Continuing treatment, trial of dose reduction or cessation of treatment<br>The condition must be characterised by psychotic symptoms and aggression; AND<br>Patient must have dementia of the Alzheimer type; AND<br>Patient must have responded to an initial course of treatment with this drug for this condition; AND<br>Patient must have failed to respond to non-pharmacological methods of treatment; AND<br>The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR | Compliance with Authority Required procedures |

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| | | | | Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically; AND<br>Patient must be optimised on non-pharmacological methods of treatment.<br>The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.<br>Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.<br>Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.<br>Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.<br>Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.<br>Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records. | |
| Ritonavir | C4454 | | | HIV infection<br>Continuing<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |
| | C4512 | | | HIV infection<br>Initial<br>Patient must be antiretroviral treatment naive; AND<br>The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4512 |

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| Rivaroxaban | C4098 | P4098 | | Deep vein thrombosis<br>Initial treatment<br>Patient must have confirmed acute symptomatic deep vein thrombosis; AND<br>Patient must not have symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4098 |
| | C4099 | | | Deep vein thrombosis<br>Continuing treatment<br>Patient must have confirmed acute symptomatic deep vein thrombosis; AND<br>Patient must not have symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4099 |
| | C4132 | P4132 | | Prevention of recurrent venous thromboembolism<br>Continuing treatment<br>Patient must have a history of venous thromboembolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4132 |
| | C4260 | P4260 | | Pulmonary embolism<br>Initial treatment<br>Patient must have confirmed acute symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4260 |
| | C4268 | | | Pulmonary embolism<br>Continuing treatment<br>Patient must have confirmed acute symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4268 |
| | C4269 | P4269 | | Prevention of stroke or systemic embolism<br>Patient must have non-valvular atrial fibrillation; AND<br>Patient must have one or more risk factors for developing stroke or systemic embolism.<br>Risk factors for developing stroke or systemic ischaemic embolism are: | Compliance with Authority Required procedures - Streamlined Authority |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;<br>(ii) age 75 years or older;<br>(iii) hypertension;<br>(iv) diabetes mellitus;<br>(v) heart failure and/or left ventricular ejection fraction 35% or less. | Code 4269 |
| | C4382 | P4382 | | Prevention of venous thromboembolism<br>Patient must be undergoing total knee replacement.<br>Patient must require up to 15 days of therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 4382 |
| | C4402 | P4402 | | Prevention of venous thromboembolism<br>Patient must be undergoing total hip replacement.<br>Patient must require up to 30 days supply to complete a course of treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 4402 |
| | C10992 | | | Chronic stable atherosclerotic disease<br>Continuing treatment<br>Patient must have received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with aspirin, but not with any other anti-platelet therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10992 |
| | C11013 | | | Chronic stable atherosclerotic disease<br>Initial treatment<br>The treatment must be in combination with aspirin, but not with any other anti-platelet therapy; AND<br>Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors: (i) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (ii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iii) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; OR | Compliance with Authority Required procedures - Streamlined Authority Code 11013 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors: (i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; AND<br>Patient must have at least one of the following if coronary artery disease is present: (i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary revascularisation procedure with significant stenosis in more than 1 coronary artery; OR<br>Patient must have at least one of the following if peripheral arterial disease is present: (i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%; AND<br>The condition must be diagnosed by at least one of: (i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication; AND<br>Patient must have clinical findings/observations by the treating physician that exclude each of the following: (i) high risk of bleeding (ii) prior stroke within one month of treatment initiation (iii) prior haemorrhagic / lacunar stroke (iv) severe heart failure with a known ejection fraction less than 30% (v) New York Heart Association class III to IV heart failure symptoms (i.e. symptoms corresponding to moderate to severe limitation on physical activity, whereby any of fatigue/palpitations/dyspnoea occur upon zero to minimal activity) (vi) an estimated glomerular filtration rate less than 15 mL/minute (vii) a requirement for dual antiplatelet therapy (viii) a requirement for non-acetylsalicylic acid antiplatelet therapy (ix) a requirement for a higher dose of oral anticoagulant therapy.<br>Must be treated by a specialist physician; OR<br>Must be treated by a physician who has consulted a specialist physician. | |
| Rivastigmine | C10099 | | | Mild to moderately severe Alzheimer disease<br>Initial 2<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND | Compliance with Written Authority Required procedures |

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| | | | | The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.<br>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.<br>Patients who qualify under this criterion are from 1 or more of the following groups:<br>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;<br>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;<br>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;<br>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;<br>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;<br>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.<br>Application through this treatment restriction must be made in writing.<br>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.<br>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised. | |
| | C10100 | | | Mild to moderately severe Alzheimer disease<br>Initial 2<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Written Authority Required procedures |

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| | | | | The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.<br>Application through this treatment restriction must be made in writing.<br>Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.<br>Where no prior approval has been issued before this application, up to a maximum of 1 month's therapy plus 5 repeats will be authorised. | |
| | C13938 | | | Mild to moderately severe Alzheimer disease<br>Continuing<br>Patient must have received six months of sole PBS-subsidised initial therapy with this drug; AND<br>Patient must demonstrate a clinically meaningful response to the initial treatment; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.<br>Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.<br>Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.<br>Clinically meaningful response to treatment is demonstrated in the following areas:<br>Patient's quality of life including but not limited to level of independence and happiness;<br>Patient's cognitive function including but not limited to memory, recognition and interest in environment;<br>Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour. | Compliance with Authority Required procedures - Streamlined Authority Code 13938 |
| | C13940 | | | Mild to moderately severe Alzheimer disease<br>Initial<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less; AND | Compliance with Authority Required procedures |

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| | | | | The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.<br>Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.<br>Patients who qualify under this criterion are from 1 or more of the following groups:<br>(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;<br>(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;<br>(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;<br>(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;<br>(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;<br>(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.<br>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. | |
| | C13941 | | | Mild to moderately severe Alzheimer disease<br>Initial<br>Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more; AND<br>The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist); AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.<br>Up to a maximum of 6 months' initial therapy will be authorised for this drug, for this strength | Compliance with Authority Required procedures |

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| | | | | under this treatment restriction. | |
| Rizatriptan | C5708 | | | Migraine attack<br>The condition must have usually failed to respond to analgesics in the past. | |
| Romosozumab | C13819 | | | Severe established osteoporosis<br>Initial treatment<br>Patient must be at very high risk of fracture; AND<br>Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND<br>Patient must have had 2 or more fractures due to minimal trauma; AND<br>Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not exceed a lifetime maximum of 12 months therapy; AND<br>Patient must not have received treatment with PBS-subsidised teriparatide; OR<br>Patient must have developed intolerance to teriparatide of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.<br>Must be treated by a consultant physician.<br>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.<br>If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with this drug is initiated.<br>If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with this drug is initiated.<br>Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, | Compliance with Authority Required procedures |

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| | | | | raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.<br>Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application. | |
| | C13820 | | | Severe established osteoporosis<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed a lifetime maximum of 12 months therapy.<br>Must be treated by a medical practitioner identifying as either: (i) a consultant physician, (ii) a general practitioner. | Compliance with Authority Required procedures |
| Rosuvastatin | | P7598 | | For use in patients who are 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. | |
| Rotigotine | C4190 | | | Parkinson disease<br>The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. | |
| | C4204 | | | Parkinson disease<br>The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. | |
| Roxithromycin | | P10404 | CN10404 | Infection<br>Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10404 |
| Ruxolitinib | C13127 | P13127 | | High risk and intermediate-2 risk myelofibrosis<br>Initial treatment<br>The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, | Compliance with Written Authority Required procedures |

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| | | | | (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report.<br>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:<br>(a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and<br>(b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.<br>All reports must be documented in the patient's medical records.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(i) A completed authority prescription form; and<br>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |
| | C13128 | P13128 | | High risk and intermediate-2 risk myelofibrosis<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| | C13130 | P13130 | | Intermediate-1 risk myelofibrosis<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| | C13173 | P13173 | | Intermediate-1 risk myelofibrosis<br>Initial treatment<br>The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report; AND<br>Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.<br>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:<br>a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and<br>b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age- | Compliance with Written Authority Required procedures |

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| | | | | Adjusted DIPSS; and<br>c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.<br>All reports must be documented in the patient's medical records.<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(i) A completed authority prescription form; and<br>(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). | |
| | C13866 | P13866 | | Moderate to severe chronic graft versus host disease (cGVHD)<br>Grandfather treatment (transition from non-PBS-subsidised treatment)<br>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND<br>Patient must have received systemic steroid treatment prior to initiation of this drug for this condition; AND<br>Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND<br>Patient must have responding disease at 24 weeks compared with baseline, demonstrated by either a: (i) partial response, (ii) complete response.<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.<br>Steroid-refractory disease is defined as:<br>(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or<br>(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).<br>Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).<br>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating | Compliance with Authority Required procedures - Streamlined Authority Code 13866 |

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

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | all evaluable organs without initiation or addition of new systemic therapy.<br>(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies.<br>The assessment of response must be documented in the patient's medical records.<br>Tapering the dose of corticosteroids should be considered in patients with responding disease.<br>Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | |
| | C13876 | P13876 | | Grade II to IV acute graft versus host disease (aGVHD)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.<br>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.<br>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.<br>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.<br>The assessment of response must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 13876 |

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

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| | | | | Details of prior steroid use should be documented in the patient's medical records.<br>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.<br>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.<br>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.<br>The assessment of response must be documented in the patient's medical records.<br>Tapering the dose of corticosteroids should be considered in patients with responding disease.<br>Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | |
| | C13891 | P13891 | | Grade II to IV acute graft versus host disease (aGVHD)<br>Grandfather treatment (transition from non-PBS-subsidised treatment)<br>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2023; AND<br>Patient must have received systemic steroid treatment prior to initiation of this drug for this condition; AND<br>Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND<br>Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.<br>Steroid-refractory disease is defined as: | Compliance with Authority Required procedures - Streamlined Authority Code 13891 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or<br>(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.<br>Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:<br>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or<br>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.<br>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.<br>Details of prior steroid use should be documented in the patient's medical records.<br>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.<br>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.<br>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.<br>The assessment of response must be documented in the patient's medical records.<br>Tapering the dose of corticosteroids should be considered in patients with responding disease.<br>Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | |
| | C13892 | P13892 | | Grade II to IV acute graft versus host disease (aGVHD) | Compliance with |

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| | | | | Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.<br>Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.<br>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.<br>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.<br>The assessment of response must be documented in the patient's medical records.<br>Tapering the dose of corticosteroids should be considered in patients with responding disease.<br>Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Authority Required procedures - Streamlined Authority Code 13892 |
| | C13906 | P13906 | | Moderate to severe chronic graft versus host disease (cGVHD)<br>Initial treatment<br>Patient must have received prior systemic steroid treatment for this condition; AND<br>Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment; AND<br>The treatment must be the sole PBS-subsidised treatment for this condition with the exception of: (i) corticosteroids, (ii) calcineurin inhibitors. | Compliance with Authority Required procedures - Streamlined Authority Code 13906 |

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| | | | | Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.<br>The severity of cGVHD is defined by the National Institutes of Health (NIH) criteria (Jagasia et al., 2015):<br>(a) Moderate cGVHD: at least one organ (not lung) with a score of 2, 3 or more organs involved with a score of 1 in each organ, or lung score of 1<br>(b) Severe cGVHD: at least 1 organ with a score of 3, or lung score of 2 or 3<br>Steroid-refractory disease is defined as:<br>(a) a lack of response or disease progression after administration of a minimum prednisone dose of 1 mg/kg/day for at least 1 week (or equivalent); or<br>(b) disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).<br>Steroid-dependent disease is defined as an increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).<br>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.<br>Details of prior steroid use should be documented in the patient's medical records.<br>A patient must demonstrate a response 24 weeks after initiating treatment with ruxolitinib to be eligible for continuing treatment.<br>Response is defined as attaining a complete or partial response as defined by the National Institutes of Health (NIH) criteria (Lee et al., 2015). Note that response is relative to the assessment of organ function affected by cGVHD prior to commencing initial treatment with ruxolitinib.<br>(a) complete response is defined as complete resolution of all signs and symptoms of cGVHD in all evaluable organs without initiation or addition of new systemic therapy.<br>(b) partial response is defined as an improvement in at least one organ (e.g. improvement of 1 or more points on a 4-to-7-point scale, or an improvement of 2 or more points on a 10-to-12-point scale) without progression in other organs or sites, initiation or addition of new systemic therapies. | |

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| | | | | The assessment of response must be documented in the patient's medical records.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | |
| | C13907 | P13907 | | Grade II to IV acute graft versus host disease (aGVHD)<br>Initial treatment<br>Patient must have received prior systemic steroid treatment for this condition; AND<br>Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment.<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.<br>The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).<br>Steroid-refractory disease is defined as:<br>(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or<br>(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.<br>Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:<br>(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or<br>(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.<br>Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.<br>Details of prior steroid use should be documented in the patient's medical records.<br>A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.<br>Response is defined as attaining a complete or partial response as assessed by Mount Sinai | Compliance with Authority Required procedures - Streamlined Authority Code 13907 |

| Listed Drug | Circumstances Code | Purposes Code | Conditions Code | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.<br>(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.<br>(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.<br>The assessment of response must be documented in the patient's medical records.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | |
| | C13911 | P13911 | | Grade II to IV acute graft versus host disease (aGVHD)<br>Initial treatment<br>Patient must have received prior systemic steroid treatment for this condition; AND<br>Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment.<br>Must be treated by a haematologist; OR<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.<br>The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).<br>Steroid-refractory disease is defined as:<br>(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or<br>(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.<br>Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the | Compliance with Authority Required procedures - Streamlined Authority Code 13911 |

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