

National Health (Listing of Pharmaceutical Benefits) Instrument 2024

PB 26 of 2024

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

National Health Act 1953

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This compilation is in 10 volumes

Volume 1: sections 1–24 and Schedule 1 (Part 1: A–C)

Volume 2: Schedule 1 (Part 1: D–K)

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: C4076–C9993)

**Volume 6: Schedule 4 (Part 1: C10020–C12999)**

Volume 7: Schedule 4 (Part 1: C13006–C13925)

Volume 8: Schedule 4 (Part 1: C13927–C14567)

Volume 9: Schedule 4 (Part 1: C14568–C16252, Part 2)

Volume 10: Schedules 5, 6 and Endnotes

Each volume has its own contents

**About this compilation**

**This compilation**

This is a compilation of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* that shows the text of the law as amended and in force on 1 January 2025 (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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Schedule 4—Circumstances, purposes, conditions and variations

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

Part 1—Circumstances, purposes and conditions

1 Circumstances, purposes and conditions

The following table sets out:

(a) circumstances for circumstances codes, for the purposes of section 13 and 23; and

(b) purposes for purposes codes, for the purposes of sections 15 and 16; and

(c) for the purposes of section 19, information relating to how authorisation is obtained when the circumstances or conditions for writing a prescription include an authorisation requirement.

| **Circumstances Code** | **Purposes Code** | **Conditions Code** | **Listed Drug** | **Circumstances and Purposes** | **Authority Requirements (part of Circumstances; or Conditions)** |
| --- | --- | --- | --- | --- | --- |
| C10020 | P10020 | CN10020 | Risperidone | Behavioural disturbances  Initial treatment  The condition must be characterised by psychotic symptoms and aggression; AND  Patient must have dementia of the Alzheimer type; AND  Patient must have failed to respond to non-pharmacological methods of treatment; AND  Patient must not receive more than 12 weeks of treatment under this restriction.  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 | CN10021 | Risperidone | Behavioural disturbances  Continuing treatment, trial of dose reduction or cessation of treatment  The condition must be characterised by psychotic symptoms and aggression; AND  Patient must have dementia of the Alzheimer type; AND  Patient must have responded to an initial course of treatment with this drug for this condition; AND  Patient must have failed to respond to non-pharmacological methods of treatment; AND  The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; or  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  Patient must be optimised on non-pharmacological methods of treatment.  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.  Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.  Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.  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.  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.  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. | Compliance with Authority Required procedures |
| C10033 | P10033 | CN10033 | Cobimetinib | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment  Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10033 |
| C10051 | P10051 | CN10051 | Trametinib | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment  Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10051 |
| C10061 | P10061 | CN10061 | Lanreotide  Octreotide | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)  The condition must be unresectable locally advanced disease or metastatic disease; AND  The condition must be World Health Organisation (WHO) grade 1 or 2; AND  The treatment must be the sole PBS-subsidised therapy for this condition;  Patient must be aged 18 years or older.  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.  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 |
| C10063 | P10063 | CN10063 | Cinacalcet | Secondary hyperparathyroidism  Continuing treatment  Must be treated by a nephrologist; AND  Patient must have chronic kidney disease; AND  Patient must be on dialysis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition.  During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.  During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability. | Compliance with Authority Required procedures - Streamlined Authority Code 10063 |
| C10067 | P10067 | CN10067 | Cinacalcet | Secondary hyperparathyroidism  Continuing treatment  Must be treated by a nephrologist; AND  Patient must have chronic kidney disease; AND  Patient must be on dialysis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition.  During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.  During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability. | Compliance with Authority Required procedures - Streamlined Authority Code 10067 |
| C10068 | P10068 | CN10068 | Cinacalcet | Secondary hyperparathyroidism  Continuing treatment  Patient must have chronic kidney disease; AND  Patient must be on dialysis; AND  Patient must have achieved a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment. or  Patient must have an intact parathyroid (iPTH) concentration greater than 15 pmol/L and an (adjusted) serum calcium concentration of less than 2.6 mmol/L after 6 months.  During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.  During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability. | Compliance with Authority Required procedures - Streamlined Authority Code 10068 |
| C10073 | P10073 | CN10073 | Cinacalcet | Secondary hyperparathyroidism  Initial treatment  Must be treated by a nephrologist; AND  Patient must have chronic kidney disease; AND  Patient must be on dialysis; AND  Patient must have failed to respond to conventional therapy; AND  Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L. or  Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L.  During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved.  During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability. | Compliance with Authority Required procedures |
| C10075 | P10075 | CN10075 | Octreotide | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The condition must be unresectable locally advanced disease or metastatic disease; AND  The condition must be World Health Organisation (WHO) grade 1 or 2; AND  The treatment must be the sole PBS-subsidised therapy for this condition;  Patient must be aged 18 years or older.  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.  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 |
| C10076 | P10076 | CN10076 | Sapropterin | Hyperphenylalaninaemia  Initial treatment  Must be treated by a metabolic physician; AND  Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.  Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
| C10077 | P10077 | CN10077 | Lanreotide  Octreotide | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)  The condition must be unresectable locally advanced disease or metastatic disease; AND  The condition must be World Health Organisation (WHO) grade 1 or 2; AND  The treatment must be the sole PBS-subsidised therapy for this condition;  Patient must be aged 18 years or older.  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.  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 |
| C10093 | P10093 | CN10093 | Fingolimod | Multiple sclerosis  Continuing treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug; AND  Patient must have demonstrated compliance with, and an ability to tolerate this therapy;  Patient must weigh 40 kg or less. | Compliance with Authority Required procedures - Streamlined Authority Code 10093 |
| C10095 | P10095 | CN10095 | Prednisolone with phenylephrine | Severe eye inflammation  Patient must have had a cataract removed in the treated eye; or  Patient must be scheduled for cataract surgery in the treated eye;  Patient must identify as Aboriginal or Torres Strait Islander. |  |
| C10116 | P10116 | CN10116 | Dolutegravir with abacavir and lamivudine | HIV infection  Continuing treatment  Patient must have previously received PBS-subsidised therapy for HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 10116 |
| C10119 | P10119 | CN10119 | Nivolumab | Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma  Initial treatment  The treatment must be adjuvant to complete surgical resection; AND  Patient must have a WHO performance status of 1 or less; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have received prior PBS-subsidised treatment for this condition; AND  The treatment must commence within 12 weeks of complete resection; AND  Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.  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 | P10120 | CN10120 | Nivolumab | Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma  Continuing treatment  Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND  Patient must not have experienced disease recurrence; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.  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 |
| C10121 | P10121 | CN10121 | Budesonide with formoterol  Fluticasone furoate with vilanterol  Fluticasone propionate with salmeterol | Chronic obstructive pulmonary disease (COPD)  Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy; AND  Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 10121 |
| C10125 | P10125 | CN10125 | Atezolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment 2  Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC); AND  Patient must have a WHO performance status of 0 or 1; AND  Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material; AND  Patient must have progressive disease following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) OR an anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI); AND  Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 10125 |
| C10130 | P10130 | CN10130 | Dabrafenib  Trametinib | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma  Continuing treatment  Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection; AND  Patient must not have experienced disease recurrence; AND  Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| C10138 | P10138 | CN10138 | Levodopa with carbidopa | Advanced Parkinson disease  Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND  The treatment must be commenced in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10138 |
| C10139 | P10139 | CN10139 | Dimethyl fumarate | Multiple sclerosis  Continuing treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug.  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10139 |
| C10140 | P10140 | CN10140 | Dimethyl fumarate | Multiple sclerosis  Initial treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND  Patient must be ambulatory (without assistance or support).  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10140 |
| C10148 | P10148 | CN10148 | Dabrafenib  Trametinib | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma  Initial treatment  The treatment must be adjuvant to complete surgical resection; AND  The condition must be positive for a BRAF V600 mutation; AND  Patient must have a WHO performance status of 1 or less; AND  Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition; AND  Patient must not have received prior PBS-subsidised treatment for this condition; AND  The treatment must commence within 12 weeks of complete resection; AND  Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| C10150 | P10150 | CN10150 | Teriflunomide | Multiple sclerosis  Initial treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND  Patient must be ambulatory (without assistance or support).  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10150 |
| C10157 | P10157 | CN10157 | Dabrafenib  Vemurafenib | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment  The condition must be positive for a BRAF V600 mutation; AND  The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; or  Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal; AND  Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma; AND  Patient must have a WHO performance status of 2 or less. | Compliance with Authority Required procedures - Streamlined Authority Code 10157 |
| C10161 | P10161 | CN10161 | Levodopa with carbidopa | Advanced Parkinson disease  Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND  The treatment must be commenced in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10161 |
| C10162 | P10162 | CN10162 | Fingolimod  Ofatumumab  Ozanimod | Multiple sclerosis  Initial treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND  Patient must be ambulatory (without assistance or support).  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10162 |
| C10170 | P10170 | CN10170 | Cladribine | Relapsing remitting multiple sclerosis  Initial treatment  The condition must be diagnosed by a neurologist; AND  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, 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  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND  Patient must be ambulatory (without assistance or support).  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.  The prescriber should write authority prescriptions for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1. | Compliance with Authority Required procedures - Streamlined Authority Code 10170 |
| C10171 | P10171 | CN10171 | Cladribine | Relapsing remitting multiple sclerosis  Continuing treatment  Must be treated by a neurologist; AND  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug; AND  Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.  The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1. | Compliance with Authority Required procedures - Streamlined Authority Code 10171 |
| C10172 | P10172 | CN10172 | Fingolimod  Ofatumumab  Ozanimod | Multiple sclerosis  Continuing treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug; AND  Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10172 |
| C10197 | P10197 | CN10197 | Levodopa with carbidopa | Advanced Parkinson disease  Maintenance therapy  Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND  Patient must have been commenced on treatment in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10197 |
| C10198 | P10198 | CN10198 | Fingolimod | Multiple sclerosis  Initial treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND  Patient must be ambulatory (without assistance or support);  Patient must weigh 40 kg or less.  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 |
| C10199 | P10199 | CN10199 | Teriflunomide | Multiple sclerosis  Continuing treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug.  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10199 |
| C10206 | P10206 | CN10206 | Atezolizumab  Durvalumab | Extensive-stage small cell lung cancer  Initial treatment  The condition must be previously untreated; AND  Patient must have a WHO performance status of 0 or 1; AND  The treatment must be in combination with etoposide and a platinum-based antineoplastic drug. | Compliance with Authority Required procedures - Streamlined Authority Code 10206 |
| C10208 | P10208 | CN10208 | Brivaracetam | Intractable partial epileptic seizures  Continuing treatment  Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND  The treatment must not be given concomitantly with levetiracetam. | Compliance with Authority Required procedures - Streamlined Authority Code 10208 |
| C10210 | P10210 | CN10210 | Brivaracetam | Intractable partial epileptic seizures  Initial treatment  Must be treated by a neurologist; AND  The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND  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  The treatment must not be given concomitantly with levetiracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 10210 |
| C10212 | P10212 | CN10212 | Trastuzumab | Early HER2 positive breast cancer  3 weekly treatment regimen  Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND  The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND  Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. or  Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.  Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10212 |
| C10213 | P10213 | CN10213 | Trastuzumab | Early HER2 positive breast cancer  Continuing treatment (weekly regimen)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND  Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. or  Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. | Compliance with Authority Required procedures - Streamlined Authority Code 10213 |
| C10215 | P10215 | CN10215 | Atezolizumab | Locally advanced or metastatic non-small cell lung cancer  Continuing treatment - 4 weekly treatment regimen  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10215 |
| C10216 | P10216 | CN10216 | Atezolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen  Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated; AND  Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment; AND  Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10216 |
| C10248 | P10248 | CN10248 | Sofosbuvir with velpatasvir and voxilaprevir | Chronic hepatitis C infection  Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND  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  The treatment must be limited to a maximum duration of 12 weeks.  The application must include details of the prior treatment regimen containing an NS5A inhibitor. The application must include details of the prior treatment regimen containing an NS5A inhibitor. | Compliance with Authority Required procedures |
| C10250 | P10250 | CN10250 | Tolvaptan | Autosomal dominant polycystic kidney disease (ADPKD)  Initial treatment  Must be treated by a nephrologist; AND  Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min 1.73 m2 at the initiation of treatment with this drug for this condition; AND  Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition.  Rapidly progressing disease is defined as either of the following  A decline in eGFR of greater than or equal to 5 mL/min/1.73 m2 within one year;  OR  An average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m2 per year over a five year period. | Compliance with Authority Required procedures |
| C10251 | P10251 | CN10251 | Brivaracetam | Intractable partial epileptic seizures  Initial treatment  Must be treated by a neurologist; AND  The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND  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  Patient must be unable to take a solid dose form of this drug; AND  The treatment must not be given concomitantly with levetiracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 10251 |
| C10252 | P10252 | CN10252 | Trifluridine with tipiracil | Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction  Initial treatment  Patient must have a WHO performance status of 1 or less; AND  Patient must have previously received at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum and either a taxane or irinotecan; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 10252 |
| C10257 | P10257 | CN10257 | Atezolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing first-line treatment of metastatic disease, as monotherapy, where concomitant bevacizumab has ceased due to intolerance - 4 weekly treatment regimen  Patient must have experienced intolerance to combination treatment with bevacizumab; AND  Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment; AND  Patient must have stable or responding disease; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10257 |
| C10268 | P10268 | CN10268 | Glecaprevir with pibrentasvir | Chronic hepatitis C infection  Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND  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  The treatment must be limited to a maximum duration of 16 weeks.  The application must include details of the prior treatment regimen containing an NS5A inhibitor. The application must include details of the prior treatment regimen containing an NS5A inhibitor. | Compliance with Authority Required procedures |
| C10271 | P10271 | CN10271 | Encorafenib | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment  The condition must be positive for a BRAF V600 mutation; AND  The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; or  Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal; AND  Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIB, IIIC or IIID melanoma; AND  Patient must have a WHO performance status of 2 or less. | Compliance with Authority Required procedures - Streamlined Authority Code 10271 |
| C10294 | P10294 | CN10294 | Trastuzumab | Early HER2 positive breast cancer  Continuing treatment (3 weekly regimen)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND  Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. or  Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. | Compliance with Authority Required procedures - Streamlined Authority Code 10294 |
| C10297 | P10297 | CN10297 | Atezolizumab | Locally advanced or metastatic non-small cell lung cancer  Continuing treatment - 3 weekly treatment regimen  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10297 |
| C10306 | P10306 | CN10306 | Binimetinib | Unresectable Stage III or Stage IV malignant melanoma  Continuing treatment  Patient must have previously been issued with an authority prescription for this drug; AND  Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition; AND  Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10306 |
| C10309 | P10309 | CN10309 | Trifluridine with tipiracil | Metastatic colorectal cancer  Initial treatment  Patient must have a WHO performance status of 1 or less; AND  Patient must have previously received treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition; or  Patient must not be a suitable candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-VEGF agent and an anti-EGFR agent for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 10309 |
| C10310 | P10310 | CN10310 | Trifluridine with tipiracil | Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10310 |
| C10317 | P10317 | CN10317 | Darunavir with cobicistat, emtricitabine and tenofovir alafenamide | HIV infection  Continuing treatment  Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner; AND  Patient must have previously received PBS-subsidised therapy for HIV infection; AND  The treatment must not be in combination with ritonavir. | Compliance with Authority Required procedures - Streamlined Authority Code 10317 |
| C10324 | P10324 | CN10324 | Darunavir with cobicistat, emtricitabine and tenofovir alafenamide | HIV infection  Initial treatment  Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner; AND  Patient must be antiretroviral treatment naive; or  Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen; AND  The treatment must not be in combination with ritonavir.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 10324 |
| C10328 | P10328 | CN10328 | Binimetinib | Unresectable Stage III or Stage IV malignant melanoma  Initial treatment  Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10328 |
| C10330 | P10330 | CN10330 | Brivaracetam | Intractable partial epileptic seizures  Continuing treatment  Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND  Patient must be unable to take a solid dose form of this drug; AND  The treatment must not be given concomitantly with levetiracetam. | Compliance with Authority Required procedures - Streamlined Authority Code 10330 |
| C10355 | P10355 | CN10355 | Sapropterin | Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency  Continuing treatment  Must be treated by a metabolic physician; or  Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND  Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition.  Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
| C10362 | P10362 | CN10362 | Tenofovir | Chronic hepatitis B infection  Patient must be in the third trimester of pregnancy; AND  Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection. | Compliance with Authority Required procedures - Streamlined Authority Code 10362 |
| C10363 | P10363 | CN10363 | Levodopa with carbidopa | Advanced Parkinson disease  Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND  The treatment must be commenced in a hospital-based movement disorder clinic; AND  Patient must require continuous administration of levodopa without an overnight break. or  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 | CN10375 | Levodopa with carbidopa | Advanced Parkinson disease  Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND  The treatment must be commenced in a hospital-based movement disorder clinic; AND  Patient must require continuous administration of levodopa without an overnight break. or  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 | CN10386 | Levodopa with carbidopa | Advanced Parkinson disease  Maintenance therapy  Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND  Patient must have been commenced on treatment in a hospital-based movement disorder clinic; AND  Patient must require continuous administration of levodopa without an overnight break. or  Patient must require a total daily dose of more than 2000 mg of levodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 10386 |
| C10388 | P10388 | CN10388 | Evolocumab | Familial homozygous hypercholesterolaemia  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in conjunction with dietary therapy and exercise. | Compliance with Authority Required procedures - Streamlined Authority Code 10388 |
| C10390 | P10390 | CN10390 | Sapropterin | Hyperphenylalaninaemia  Continuing treatment  Must be treated by a metabolic physician; or  Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND  Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition.  Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
| C10391 | P10391 | CN10391 | Sapropterin | Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency  Initial treatment  Must be treated by a metabolic physician; AND  Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.  Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured. | Compliance with Authority Required procedures |
| C10402 | P10402 | CN10402 | Amoxicillin | Infection  Patient must be a male with acute cystitis. or  Patient must have pyelonephritis. or  Patient must have a tooth avulsion. or  Patient must have salmonella enteritis. or  Patient must have community acquired pneumonia. or  Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10402 |
| C10404 | P10404 | CN10404 | Amoxicillin  Roxithromycin | Infection  Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10404 |
| C10405 | P10405 | CN10405 | Amoxicillin with clavulanic acid | Infection  Patient must be a male with acute cystitis. or  Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10405 |
| C10410 | P10410 | CN10410 | Cefalexin | Infection  Patient must have a pin-site infection. or  Patient must have an infection following cardiac device insertion. or  Patient must have acute otitis externa. or  Patient must have streptococcal pharyngitis or tonsillitis. or  Patient must have mastitis. or  Patient must have periorbital (preseptal) cellulitis. or  Patient must have acute rheumatic fever. or  Patient must have a diabetic foot infection. or  Patient must have a widespread infection of dermatitis.  Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection. or  Patient must have impetigo. or  Patient must have pyelonephritis. or  Patient must have a condition requiring prolonged oral antibiotic therapy. or  Midwives may prescribe under this item for the treatment of mastitis only. | Compliance with Authority Required procedures - Streamlined Authority Code 10410 |
| C10412 | P10412 | CN10412 | Cefalexin | Infection  Patient must have impaired renal function; AND  Patient must have a pin-site infection. or  Patient must have an infection following cardiac device insertion. or  Patient must have acute otitis externa. or  Patient must have streptococcal pharyngitis or tonsillitis. or  Patient must have mastitis. or  Patient must have periorbital (preseptal) cellulitis. or  Patient must have acute rheumatic fever. or  Patient must have a diabetic foot infection. or  Patient must have a widespread infection of dermatitis.  Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection. or  Patient must have impetigo. or  Patient must have pyelonephritis. or  Patient must have a condition requiring prolonged oral antibiotic therapy. or  Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function. | Compliance with Authority Required procedures - Streamlined Authority Code 10412 |
| C10413 | P10413 | CN10413 | Amoxicillin with clavulanic acid | Infection  Patient must have periorbital (preseptal) cellulitis. or  Patient must have postpartum endometritis. or  Patient must have an exacerbation of bronchiectasis. or  Patient must have pyelonephritis. or  Patient must have pneumonia acquired in hospital or aged care. or  Patient must have a diabetic foot infection. or  Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10413 |
| C10414 | P10414 | CN10414 | Pertuzumab | Metastatic (Stage IV) HER2 positive breast cancer  Continuing treatment  Patient must have previously been issued with an authority prescription for this drug for this condition; AND  Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND  The treatment must be in combination with trastuzumab; AND  The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.  The treatment must not exceed a lifetime total of one 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.  Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment. | Compliance with Authority Required procedures |
| C10416 | P10416 | CN10416 | Amoxicillin | Community acquired pneumonia  Patient must have community acquired pneumonia. | Compliance with Authority Required procedures - Streamlined Authority Code 10416 |
| C10431 | P10431 | CN10431 | Certolizumab pegol  Secukinumab | Non-radiographic axial spondyloarthritis  Continuing treatment  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND  The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.  An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following  (a) a CRP measurement no greater than 10 mg per L; or  (b) a CRP measurement reduced by at least 20% from baseline.  If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.  The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. | Compliance with Authority Required procedures |
| C10434 | P10434 | CN10434 | Bimekizumab  Golimumab  Upadacitinib | Non-radiographic axial spondyloarthritis  Continuing treatment - balance of supply  Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C10436 | P10436 | CN10436 | Golimumab | Non-radiographic axial spondyloarthritis  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  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C10459 | P10459 | CN10459 | Certolizumab pegol | Non-radiographic axial spondyloarthritis  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  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment; AND  The treatment must provide no more than the balance of up to 20 weeks treatment; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C10464 | P10464 | CN10464 | Budesonide with formoterol | Mild asthma  Patient must have asthma and require an anti-inflammatory reliever therapy; AND  Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).  Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine. | Compliance with Authority Required procedures - Streamlined Authority Code 10464 |
| C10482 | P10482 | CN10482 | Budesonide with formoterol | Mild asthma  Patient must have asthma and require an anti-inflammatory reliever therapy; AND  Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA);  Patient must be aged 12 years or over.  Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine. | Compliance with Authority Required procedures - Streamlined Authority Code 10482 |
| C10498 | P10498 | CN10498 | Granisetron | Nausea and vomiting  The condition must be associated with radiotherapy being used to treat malignancy. or  The condition must be associated with oral chemotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 10498 |
| C10509 | P10509 | CN10509 | Atezolizumab  Durvalumab | Extensive-stage small cell lung cancer  Continuing treatment - 4 weekly treatment regimen  The treatment must be as monotherapy; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10509 |
| C10521 | P10521 | CN10521 | Atezolizumab | Extensive-stage small cell lung cancer  Continuing treatment - 3 weekly treatment regimen  The treatment must be as monotherapy; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10521 |
| C10538 | P10538 | CN10538 | Budesonide with formoterol | Asthma  Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition; AND  Must be treated by a respiratory physician. or  Must be treated by a paediatrician. | Compliance with Authority Required procedures - Streamlined Authority Code 10538 |
| C10560 | P10560 | CN10560 | Tocilizumab | Systemic juvenile idiopathic arthritis  Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months) - in a patient of any weight being administered a subcutaneous form of this biological medicine  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; AND  Must be treated by a rheumatologist. or  Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. | Compliance with Authority Required procedures |
| C10676 | P10676 | CN10676 | Pembrolizumab | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma  Continuing treatment - 6 weekly treatment regimen  Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND  Patient must not have experienced disease recurrence; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| C10688 | P10688 | CN10688 | Pembrolizumab | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma  Initial treatment - 6 weekly treatment regimen  The treatment must be adjuvant to complete surgical resection; AND  Patient must have a WHO performance status of 1 or less; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have received prior PBS-subsidised treatment for this condition; AND  The treatment must commence within 12 weeks of complete resection; AND  Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| C10701 | P10701 | CN10701 | Pembrolizumab | Unresectable Stage III or Stage IV malignant melanoma  Continuing treatment - 6 weekly treatment regimen  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have previously been issued with an authority prescription for this drug for this condition; AND  Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10701 |
| C10705 | P10705 | CN10705 | Pembrolizumab | Unresectable Stage III or Stage IV malignant melanoma  Continuing treatment - 3 weekly treatment regimen  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have previously been issued with an authority prescription for this drug for this condition; AND  Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10705 |
| C10742 | P10742 | CN10742 | Guselkumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C10743 | P10743 | CN10743 | Guselkumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C10748 | P10748 | CN10748 | Buprenorphine  Morphine  Oxycodone  Oxycodone with naloxone  Tapentadol  Tramadol | Chronic severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months  The condition must require daily, continuous, long term opioid treatment; AND  Patient must have cancer pain. or  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or  Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | Compliance with Authority Required procedures - Streamlined Authority Code 10748 |
| C10752 | P10752 | CN10752 | Buprenorphine  Morphine  Oxycodone  Oxycodone with naloxone  Tapentadol  Tramadol | Chronic severe pain  Continuing PBS treatment after 1 June 2020  Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | Compliance with Authority Required procedures - Streamlined Authority Code 10752 |
| C10755 | P10755 | CN10755 | Buprenorphine  Morphine  Oxycodone  Oxycodone with naloxone  Tapentadol  Tramadol | Chronic severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months  The condition must require daily, continuous, long term opioid treatment; AND  Patient must have cancer pain. or  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or  Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. | Compliance with Authority Required procedures - Streamlined Authority Code 10755 |
| C10756 | P10756 | CN10756 | Morphine | Chronic severe disabling pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months  The condition must require daily, continuous, long term opioid treatment; AND  Patient must have cancer pain. or  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or  Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. | Compliance with Authority Required procedures |
| C10758 | P10758 | CN10758 | Hydromorphone | Severe pain  The treatment must be for short term therapy of acute severe pain; AND  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |  |
| C10762 | P10762 | CN10762 | Morphine | Severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. or  The treatment must be part of pre-operative care. or  The treatment must be used as an analgesic adjunct in general anaesthesia.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. |  |
| C10764 | P10764 | CN10764 | Codeine  Codeine with paracetamol  Hydromorphone  Morphine  Oxycodone  Tramadol | Severe pain  Continuing PBS treatment after 1 June 2020  Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. |  |
| C10765 | P10765 | CN10765 | Morphine | Severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. or  The treatment must be part of pre-operative care. or  The treatment must be used as an analgesic adjunct in general anaesthesia. |  |
| C10766 | P10766 | CN10766 | Codeine  Codeine with paracetamol  Oxycodone  Tramadol | Severe pain  The treatment must be for short term therapy of acute severe pain; AND  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or  Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |  |
| C10768 | P10768 | CN10768 | Codeine  Codeine with paracetamol  Oxycodone  Tramadol | Severe pain  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or  Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |  |
| C10770 | P10770 | CN10770 | Hydromorphone  Morphine | Severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. |  |
| C10771 | P10771 | CN10771 | Codeine  Codeine with paracetamol  Oxycodone  Tramadol | Severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or  Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |  |
| C10772 | P10772 | CN10772 | Codeine  Codeine with paracetamol  Oxycodone  Tramadol | Severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or  Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. |  |
| C10775 | P10775 | CN10775 | Morphine | Cancer pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months  Patient must have cancer pain; AND  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. |  |
| C10777 | P10777 | CN10777 | Hydromorphone  Morphine | Severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |  |
| C10802 | P10802 | CN10802 | Tildrakizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C10806 | P10806 | CN10806 | Guselkumab  Tildrakizumab | Severe chronic plaque psoriasis  Continuing treatment, Whole body  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C10807 | P10807 | CN10807 | Bimekizumab  Guselkumab  Tildrakizumab | Severe chronic plaque psoriasis  Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply  Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C10814 | P10814 | CN10814 | Morphine | Chronic severe disabling pain  Continuing PBS treatment after 1 June 2020  Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | Compliance with Authority Required procedures |
| C10830 | P10830 | CN10830 | Apomorphine | Parkinson disease  Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND  The treatment must be commenced in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 10830 |
| C10836 | P10836 | CN10836 | Morphine | Chronic severe disabling pain  The condition must require daily, continuous, long term opioid treatment; AND  Patient must have cancer pain. or  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or  Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. | Compliance with Authority Required procedures |
| C10837 | P10837 | CN10837 | Morphine | Cancer pain  Continuing PBS treatment after 1 June 2020  Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. |  |
| C10839 | P10839 | CN10839 | Morphine | Severe pain  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. or  The treatment must be part of pre-operative care. or  The treatment must be used as an analgesic adjunct in general anaesthesia. |  |
| C10844 | P10844 | CN10844 | Apomorphine | Parkinson disease  Maintenance therapy  Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND  Patient must have been commenced on treatment in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 10844 |
| C10853 | P10853 | CN10853 | Tildrakizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C10858 | P10858 | CN10858 | Morphine | Chronic severe disabling pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months  The condition must require daily, continuous, long term opioid treatment; AND  Patient must have cancer pain. or  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or  Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | Compliance with Authority Required procedures |
| C10859 | P10859 | CN10859 | Hydromorphone  Morphine | Severe pain  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |  |
| C10860 | P10860 | CN10860 | Oxycodone | Severe pain  The treatment must be for post-operative pain following a major operative procedure; AND  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or  Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |  |
| C10863 | P10863 | CN10863 | Apomorphine | Parkinson disease  Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND  The treatment must be commenced in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 10863 |
| C10889 | P10889 | CN10889 | Guselkumab  Tildrakizumab | Severe chronic plaque psoriasis  Continuing treatment, Face, hand, foot  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C10890 | P10890 | CN10890 | Oxycodone | Severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months  Patient must have cancer pain; or  The treatment must be for post-operative pain following a major operative procedure; AND  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or  Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. |  |
| C10891 | P10891 | CN10891 | Morphine | Cancer pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months  Patient must have cancer pain; AND  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |  |
| C10901 | P10901 | CN10901 | Guselkumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C10910 | P10910 | CN10910 | Oxycodone | Severe pain  Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months  Patient must have cancer pain; or  The treatment must be for post-operative pain following a major operative procedure; AND  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or  Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |  |
| C10917 | P10917 | CN10917 | Atezolizumab | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen  Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition.  PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time | Compliance with Authority Required procedures - Streamlined Authority Code 10917 |
| C10935 | P10935 | CN10935 | Armodafinil  Modafinil | Narcolepsy  Initial 2 - treatment of narcolepsy with cataplexy  Must be treated by a qualified sleep medicine practitioner or neurologist; AND  The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; or  The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal; AND  Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months; AND  Patient must have a definite history of cataplexy documented in their medical records for auditing purposes; AND  Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.  The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk  (a) a psychiatric disorder;  (b) a cardiovascular disorder;  (c) a history of substance abuse;  (d) glaucoma;  (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information. | Compliance with Authority Required procedures |
| C10939 | P10939 | CN10939 | Atezolizumab | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  Initial treatment  Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated; AND  Patient must have a WHO performance status of 0 or 1; AND  Patient must not be suitable for transarterial chemoembolisation; AND  Patient must have Child Pugh class A; AND  The condition must be untreated with systemic therapy. or  Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal. | Compliance with Authority Required procedures - Streamlined Authority Code 10939 |
| C10953 | P10953 | CN10953 | Siponimod | Multiple sclerosis  Continuing treatment (including recommencement of treatment)  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug; AND  Patient must be ambulatory, with/without assistance/support; AND  Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10953 |
| C10955 | P10955 | CN10955 | Siponimod | Multiple sclerosis  Initial treatment  The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord; or  The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND  Patient must be ambulatory, with/without assistance/support; AND  Patient must have mild disability in at least 3 functional systems. or  Patient must have moderate disability in at least 1 functional system.  Functional systems referred to in this restriction are the visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems.  Select a dose and pack size appropriate for the patient's CYP2C9 metabolising enzyme status. | Compliance with Authority Required procedures - Streamlined Authority Code 10955 |
| C10967 | P10967 | CN10967 | Armodafinil | Narcolepsy  Continuing or change of treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition. or  Patient must have previously received PBS-subsidised treatment with modafinil for this condition. | Compliance with Authority Required procedures |
| C10968 | P10968 | CN10968 | Modafinil | Narcolepsy  Continuing or change of treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition. or  Patient must have previously received PBS-subsidised treatment with armodafinil for this condition. | Compliance with Authority Required procedures |
| C10970 | P10970 | CN10970 | Armodafinil  Modafinil | Narcolepsy  Initial 1 - treatment of narcolepsy without cataplexy  Must be treated by a qualified sleep medicine practitioner or neurologist; AND  The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; or  The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal; AND  Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months; AND  Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); or  Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; AND  Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.  The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk  (a) a psychiatric disorder;  (b) a cardiovascular disorder;  (c) a history of substance abuse;  (d) glaucoma;  (e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.  The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.  The authority application must be made in writing and must include the following  (a) a completed authority prescription form; and  (b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and  (c) details of the contraindication or intolerance to dexamfetamine sulfate; and  (d) either  (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  (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.  The polysomnography, MSLT or EEG test reports must be provided with the authority application. | Compliance with Written Authority Required procedures |
| C10971 | P10971 | CN10971 | Methoxsalen | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma  Initial treatment  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  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  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; or  The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND  Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND  Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication; AND  Must be treated by a haematologist; or  Must be treated by a medical physician working under the supervision of a haematologist;  Patient must be aged 18 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 10971 |
| C10972 | P10972 | CN10972 | Atezolizumab | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition.  PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time | Compliance with Authority Required procedures - Streamlined Authority Code 10972 |
| C10985 | P10985 | CN10985 | Methoxsalen | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma  Initial treatment  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  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  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; or  The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND  Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND  Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication; AND  Must be treated by a haematologist; or  Must be treated by a medical physician working under the supervision of a haematologist;  Patient must be aged 18 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 10985 |
| C10988 | P10988 | CN10988 | Methoxsalen | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma  Continuing treatment  Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND  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  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; or  The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND  Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule; AND  Must be treated by a haematologist. or  Must be treated by a medical physician working under the supervision of a haematologist.  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 10988 |
| C10989 | P10989 | CN10989 | Methoxsalen | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma  Continuing treatment  Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND  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  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; or  The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND  Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule; AND  Must be treated by a haematologist. or  Must be treated by a medical physician working under the supervision of a haematologist.  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 |
| C10992 | P10992 | CN10992 | Rivaroxaban | Chronic stable atherosclerotic disease  Continuing treatment  Patient must have received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with aspirin, but not with any other anti-platelet therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10992 |
| C10995 | P10995 | CN10995 | Venetoclax | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)  Dose modification  The treatment must be for dose titration purposes. | Compliance with Authority Required procedures |
| C11013 | P11013 | CN11013 | Rivaroxaban | Chronic stable atherosclerotic disease  Initial treatment  The treatment must be in combination with aspirin, but not with any other anti-platelet therapy; AND  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  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  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  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  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  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; AND  Must be treated by a specialist physician. or  Must be treated by a physician who has consulted a specialist physician. | Compliance with Authority Required procedures - Streamlined Authority Code 11013 |
| C11015 | P11015 | CN11015 | Obinutuzumab | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)  For combination use with venetoclax treatment cycles 1 to 6 inclusive in first-line therapy  The condition must be untreated; AND  The treatment must be in combination with PBS-subsidised venetoclax. | Compliance with Authority Required procedures - Streamlined Authority Code 11015 |
| C11017 | P11017 | CN11017 | Venetoclax | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)  First continuing treatment (treatment cycles 2 to 6 inclusive) of first-line therapy  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses); AND  The treatment must cease upon disease progression. | Compliance with Authority Required procedures |
| C11057 | P11057 | CN11057 | Beclometasone with formoterol | Asthma  Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids;  Patient must be aged 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 11057 |
| C11066 | P11066 | CN11066 | Dolutegravir with lamivudine | HIV infection  Continuing or change of treatment  Patient must have previously received PBS-subsidised therapy for HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 11066 |
| C11069 | P11069 | CN11069 | Venetoclax | Chronic lymphocytic leukaemia (CLL)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy; AND  The treatment must be ceased on disease progression or on completion of 24 months of PBS-subsidised treatment under this restriction with this drug for this condition, whichever comes first. | Compliance with Authority Required procedures |
| C11070 | P11070 | CN11070 | Protein formula with vitamins and minerals, and low in potassium, phosphorus, calcium, chloride and vitamin A | Chronic renal failure  Patient must be a child aged 3 years or older;  Patient must require treatment with a low protein and a low phosphorus diet. or  Patient must require treatment with a low protein, low phosphorus and low potassium diet. | Compliance with Authority Required procedures - Streamlined Authority Code 11070 |
| C11077 | P11077 | CN11077 | Levetiracetam | Partial epileptic seizures  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or  Patient must be a woman of childbearing potential; AND  Patient must be unable to take a solid dose form of levetiracetam; AND  The treatment must not be given concomitantly with brivaracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 11077 |
| C11081 | P11081 | CN11081 | Lamotrigine | Epileptic seizures  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. or  Patient must be a woman of childbearing potential. | Compliance with Authority Required procedures - Streamlined Authority Code 11081 |
| C11089 | P11089 | CN11089 | Ixekizumab  Secukinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C11090 | P11090 | CN11090 | Tildrakizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |
| C11096 | P11096 | CN11096 | Ixekizumab  Secukinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11099 | P11099 | CN11099 | Bortezomib | Multiple myeloma |  |
| C11107 | P11107 | CN11107 | Adalimumab  Etanercept  Ixekizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or 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  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  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  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  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  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  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  The treatment must be as systemic monotherapy (other than methotrexate); AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C11116 | P11116 | CN11116 | Levetiracetam | Partial epileptic seizures  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or  Patient must be a woman of childbearing potential; AND  The treatment must not be given concomitantly with brivaracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 11116 |
| C11119 | P11119 | CN11119 | Ustekinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11120 | P11120 | CN11120 | Tildrakizumab  Ustekinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or 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  Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction; AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C11123 | P11123 | CN11123 | Tildrakizumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | Compliance with Written Authority Required procedures |
| C11130 | P11130 | CN11130 | Guselkumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11138 | P11138 | CN11138 | Ixekizumab  Secukinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11143 | P11143 | CN11143 | Tenofovir with emtricitabine | Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection  Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued:   (i) a negative HIV test result no older than 4 weeks, (ii) evidence that an HIV test has been conducted, but the result is still forthcoming. |  |
| C11145 | P11145 | CN11145 | Ustekinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C11153 | P11153 | CN11153 | Ustekinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11154 | P11154 | CN11154 | Ixekizumab  Secukinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C11160 | P11160 | CN11160 | Sorafenib | Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  Initial treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have a WHO performance status of 2 or less; AND  Patient must have Child Pugh class A; AND  The condition must be untreated with systemic therapy. or  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 11160 |
| C11161 | P11161 | CN11161 | Ustekinumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C11168 | P11168 | CN11168 | Lenvatinib | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  Initial treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not be suitable for transarterial chemoembolisation; AND  Patient must have a WHO performance status of 2 or less; AND  Patient must have Child Pugh class A; AND  The condition must be untreated with systemic therapy. or  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 |
| C11310 | P11310 | CN11310 | Esomeprazole  Lansoprazole  Omeprazole  Pantoprazole  Rabeprazole | Complex gastro-oesophageal reflux disease (GORD)  One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control  Must be treated by a gastroenterologist; or  Must be treated by a surgeon with expertise in the upper gastrointestinal tract; or  Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; or  Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes; AND  The treatment must be:   (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND  Patient must must have symptoms inadequately controlled with each of:   (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control. or  Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for:   (2) maintenance treatment. or  Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for:   (3) re-establishment of symptom control. or  Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for:   (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.  Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction. | Compliance with Authority Required procedures |
| C11360 | P11360 | CN11360 | Indacaterol with mometasone | Asthma  Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids;  Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 11360 |
| C11370 | P11370 | CN11370 | Esomeprazole | Complex gastro-oesophageal reflux disease (GORD)  One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control  Must be treated by a gastroenterologist; or  Must be treated by a surgeon with expertise in the upper gastrointestinal tract; AND  The treatment must be:   (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND  Patient must have symptoms inadequately controlled with each of:   (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control. or  Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for:   (2) maintenance treatment. or  Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for:   (3) re-establishment of symptom control. or  Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for:   (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.  Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction. | Compliance with Authority Required procedures |
| C11374 | P11374 | CN11374 | Dupilumab | Chronic severe atopic dermatitis  Continuing or resuming treatment of the whole body  Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body; AND  Patient must have achieved an adequate response within the first 16 weeks of treatment; or  Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; or  Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application; AND  The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND  Must be treated by a dermatologist. or  Must be treated by a clinical immunologist.  For the purposes of this restriction, an adequate response to treatment is defined as  (a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and  (b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline  Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.  State each of the current EASI and DLQI scores for this authority application. | Compliance with Authority Required procedures |
| C11377 | P11377 | CN11377 | Dupilumab | Chronic severe atopic dermatitis  Continuing or resuming treatment of the face and/or hands  Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands; AND  Patient must have achieved an adequate response within the first 16 weeks of treatment; or  Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; or  Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application; AND  The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND  Must be treated by a dermatologist. or  Must be treated by a clinical immunologist.  For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as  (a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or  (ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and  (b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline  Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.  Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes | Compliance with Authority Required procedures |
| C11385 | P11385 | CN11385 | Apomorphine | Parkinson disease  Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND  The treatment must be commenced in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 11385 |
| C11390 | P11390 | CN11390 | Secukinumab | Non-radiographic axial spondyloarthritis  Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patients) restriction to complete 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; AND  The treatment must provide no more than the balance of up to 20 weeks treatment; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C11391 | P11391 | CN11391 | Ipilimumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing combination treatment (with nivolumab) of first-line drug therapy  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND  The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND  The treatment must be in combination with nivolumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11391 |
| C11445 | P11445 | CN11445 | Apomorphine | Parkinson disease  Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND  The treatment must be commenced in a specialist unit in a hospital setting. | Compliance with Authority Required procedures - Streamlined Authority Code 11445 |
| C11468 | P11468 | CN11468 | Nivolumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Continuing combination treatment (with ipilimumab) of first-line drug therapy  The condition must be squamous type non-small cell lung cancer (NSCLC); AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND  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  The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11468 |
| C11473 | P11473 | CN11473 | Fulvestrant | Locally advanced or metastatic breast cancer  The condition must be hormone receptor positive; AND  The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND  The condition must be inoperable;  Patient must not be premenopausal.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 11473 |
| C11477 | P11477 | CN11477 | Nivolumab | Locally advanced or metastatic non-small cell lung cancer  Continuing treatment as second-line drug therapy  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  Patient must have stable or responding disease.  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 11477 |
| C11478 | P11478 | CN11478 | Ipilimumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial combination treatment (with nivolumab) as first-line drug therapy  The condition must be squamous type non-small cell lung cancer (NSCLC); AND  Patient must not have previously been treated for this condition in the metastatic setting; AND  Patient must have a WHO performance status of 0 or 1; AND  The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND  The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND  The treatment must be in combination with nivolumab.  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 11478 |
| C11482 | P11482 | CN11482 | Amino acid formula with vitamins and minerals without lysine and low in tryptophan | Pyridoxine dependent epilepsy  Patient must be managed on a low lysine diet for pyridoxine dependent epilepsy; AND  The condition must be treated by or in consultation with a metabolic physician. |  |
| C11523 | P11523 | CN11523 | Adalimumab | Severe psoriatic arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11523 |
| C11524 | P11524 | CN11524 | Adalimumab | Complex refractory Fistulising Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND  Patient must have demonstrated an adequate response to treatment with this drug for this condition.  An adequate response is defined as  (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  A maximum of 24 weeks treatment will be authorised under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11524 |
| C11529 | P11529 | CN11529 | Adalimumab | Moderate to severe hidradenitis suppurativa  Subsequent continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated a response to treatment with this drug for this condition; AND  Must be treated by a dermatologist.  A response to treatment is defined as  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 11529 |
| C11579 | P11579 | CN11579 | Adalimumab | Moderate to severe ulcerative colitis  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated 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; or  Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be 6 years of age or older.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Authority Required procedures - Streamlined Authority Code 11579 |
| C11604 | P11604 | CN11604 | Adalimumab | Severe active juvenile idiopathic arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. | Compliance with Authority Required procedures - Streamlined Authority Code 11604 |
| C11606 | P11606 | CN11606 | Adalimumab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Face, hand, foot  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11606 |
| C11631 | P11631 | CN11631 | Adalimumab | Severe Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or  Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11631 |
| C11635 | P11635 | CN11635 | Adalimumab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Whole body  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 11635 |
| C11642 | P11642 | CN11642 | Stiripentol | Severe myoclonic epilepsy in infancy (Dravet syndrome)  Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs; AND  The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs; AND  Must be treated by a neurologist if treatment is being initiated. or  Must be treated by a neurologist if treatment is being continued or re-initiated. or  Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued. or  Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued. | Compliance with Authority Required procedures - Streamlined Authority Code 11642 |
| C11644 | P11644 | CN11644 | High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate | Ketogenic diet  Patient must have intractable seizures requiring treatment with a ketogenic diet; or  Patient must have a glucose transport protein defect; or  Patient must have pyruvate dehydrogenase deficiency; AND  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. |  |
| C11673 | P11673 | CN11673 | Progesterone | Prevention of preterm birth  Patient must have a singleton pregnancy; AND  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  The treatment must be administered no earlier than at 16 weeks gestation. | Compliance with Authority Required procedures - Streamlined Authority Code 11673 |
| C11680 | P11680 | CN11680 | Sacubitril with valsartan | Chronic heart failure  Patient must be symptomatic with NYHA classes II, III or IV; AND  Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND  Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker:   (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker; AND  Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; or  Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND  The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist. | Compliance with Authority Required procedures - Streamlined Authority Code 11680 |
| C11681 | P11681 | CN11681 | Cannabidiol | Severe myoclonic epilepsy in infancy (Dravet syndrome)  Patient must have (as an initiating patient)/have had (as a continuing patient), generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with at least two other anti-epileptic drugs; AND  The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs; AND  Must be treated by a neurologist if treatment is being initiated. or  Must be treated by a neurologist if treatment is being continued or re-initiated. or  Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued. or  Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued. | Compliance with Authority Required procedures |
| C11683 | P11683 | CN11683 | Clonazepam  Haloperidol  Metoclopramide | For use in patients receiving palliative care |  |
| C11696 | P11696 | CN11696 | Fentanyl  Methadone | Severe disabling pain  Patient must not be opioid naive; AND  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; AND  Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| C11697 | P11697 | CN11697 | Hydromorphone  Morphine | Severe pain  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or  Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; AND  Patient must be undergoing palliative care. | Compliance with Authority Required procedures - Streamlined Authority Code 11697 |
| C11704 | P11704 | CN11704 | Adalimumab | Severe Crohn disease  First continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or  Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C11709 | P11709 | CN11709 | Adalimumab | Severe Crohn disease  Balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment. or  The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment. | Compliance with Authority Required procedures |
| C11711 | P11711 | CN11711 | Adalimumab | Severe Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or  Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C11713 | P11713 | CN11713 | Adalimumab | Severe Crohn disease  Balance of supply for paediatric patient  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; or  The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment; AND  Must be treated by a gastroenterologist (code 87). or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or  Must be treated by a paediatrician. or  Must be treated by a specialist paediatric gastroenterologist. | Compliance with Authority Required procedures |
| C11715 | P11715 | CN11715 | Adalimumab | Severe Crohn disease  Initial treatment - Initial 1 (new patient)  Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND  Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:   (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; or  Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate; AND  Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment and which is no more than 4 weeks old at the time of application; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive;  Must be treated by a gastroenterologist (code 87). or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or  Must be treated by a paediatrician. or  Must be treated by a specialist paediatric gastroenterologist.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website (www.servicesaustralia.gov.au).  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
| C11716 | P11716 | CN11716 | Adalimumab | Severe Crohn disease  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist; AND  Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive;  Must be treated by a gastroenterologist (code 87). or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or  Must be treated by a paediatrician. or  Must be treated by a specialist paediatric gastroenterologist.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  The PCDAI assessment must be no more than 4 weeks old at the time of application.  A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
| C11717 | P11717 | CN11717 | Adalimumab | Severe Crohn disease  Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI  Patient must have a documented history of severe Crohn disease; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND  Patient must have a total PCDAI score of 40 points or less; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive;  Must be treated by a gastroenterologist (code 87). or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or  Must be treated by a paediatrician. or  Must be treated by a specialist paediatric gastroenterologist.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  The PCDAI assessment must be no more than 4 weeks old at the time of application.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C11718 | P11718 | CN11718 | Adalimumab | Severe Crohn disease  Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI  Patient must have a documented history of severe Crohn disease; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND  Patient must have a total PCDAI score of 40 points or less; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive;  Must be treated by a gastroenterologist (code 87). or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or  Must be treated by a paediatrician. or  Must be treated by a specialist paediatric gastroenterologist.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  The PCDAI assessment must be no more than 4 weeks old at the time of application.  Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. | Compliance with Authority Required procedures - Streamlined Authority Code 11718 |
| C11746 | P11746 | CN11746 | Clonazepam | For use in patients receiving palliative care |  |
| C11753 | P11753 | CN11753 | Buprenorphine  Morphine  Oxycodone  Oxycodone with naloxone | Severe disabling pain  Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; or  Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance; AND  Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| C11755 | P11755 | CN11755 | Obinutuzumab | Follicular lymphoma  Re-induction treatment  Patient must not have previously received PBS-subsidised obinutuzumab; AND  The condition must be CD20 positive; AND  The condition must be refractory to treatment with rituximab for this condition; AND  The condition must be symptomatic; AND  The treatment must be for re-induction treatment purposes only; AND  The treatment must be in combination with bendamustine; AND  The treatment must not exceed 8 doses for re-induction treatment with this drug for this condition.  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.  A patient may only qualify for PBS-subsidised initiation treatment once in a lifetime under  i) the previously untreated induction treatment restriction; or  ii) the rituximab-refractory re-induction restriction. | Compliance with Authority Required procedures |
| C11759 | P11759 | CN11759 | Adalimumab | Severe Crohn disease  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C11761 | P11761 | CN11761 | Adalimumab | Severe Crohn disease  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have a documented history of severe Crohn disease; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive;  Must be treated by a gastroenterologist (code 87). or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or  Must be treated by a paediatrician. or  Must be treated by a specialist paediatric gastroenterologist.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
| C11762 | P11762 | CN11762 | Adalimumab | Severe Crohn disease  Initial treatment - Initial 1 (new patient)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];  Patient must be aged 18 years or older;  Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND  Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND  Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; or  Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; or  Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND  Patient must not receive more than 16 weeks of treatment under this restriction; AND  Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy. or  Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. or  Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following  (a) patient must have evidence of intestinal inflammation;  (b) patient must be assessed clinically as being in a high faecal output state;  (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.  (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or  (ii) faeces higher than normal lactoferrin or calprotectin level; or  (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.  Evidence of intestinal inflammation includes  (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or  (ii) faeces higher than normal lactoferrin or calprotectin level; or  (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.  Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.  All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.  If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.  If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.  Details of the accepted toxicities including severity can be found on the Services Australia website.  Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C11763 | P11763 | CN11763 | Adalimumab | Severe Crohn disease  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND  Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; or  Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; or  Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND  Patient must have evidence of intestinal inflammation; or  Patient must be assessed clinically as being in a high faecal output state; or  Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  Evidence of intestinal inflammation includes  (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or  (ii) faeces higher than normal lactoferrin or calprotectin level; or  (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.  Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested under the balance of supply restriction.  Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C11767 | P11767 | CN11767 | Adalimumab | Severe Crohn disease  First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI  Patient must have a documented history of severe Crohn disease; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND  Patient must have a total PCDAI score of 40 points or less; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive;  Must be treated by a gastroenterologist (code 87). or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or  Must be treated by a paediatrician. or  Must be treated by a specialist paediatric gastroenterologist.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  The PCDAI assessment must be no more than 4 weeks old at the time of application.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C11784 | P11784 | CN11784 | Botulinum toxin type A purified neurotoxin complex | Chronic migraine  Must be treated by a neurologist; AND  Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin; AND  Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin; AND  Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment; AND  Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin;  Patient must be aged 18 years or older.  Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate. | Compliance with Authority Required procedures - Streamlined Authority Code 11784 |
| C11785 | P11785 | CN11785 | Obinutuzumab | Follicular lymphoma  Maintenance therapy  Patient must have previously received PBS-subsidised treatment with this drug under the rituximab refractory initial restriction; AND  The condition must be CD20 positive; AND  The condition must have been refractory to treatment with rituximab; AND  Patient must have demonstrated a partial or complete response to PBS-subsidised re-induction treatment with this drug for this condition; AND  The treatment must be maintenance therapy; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C11787 | P11787 | CN11787 | Obinutuzumab | Stage II bulky or Stage III/IV follicular lymphoma  Maintenance therapy  Patient must have previously received PBS-subsidised treatment with this drug under the previously untreated initial restriction; AND  The condition must be CD20 positive; AND  Patient must have demonstrated a partial or complete response to PBS subsidised induction treatment with this drug for this condition; AND  The treatment must be maintenance therapy; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C11815 | P11815 | CN11815 | Obinutuzumab | Stage II bulky or Stage III/IV follicular lymphoma  Induction treatment  The condition must be CD20 positive; AND  The condition must be previously untreated; AND  The condition must be symptomatic; AND  The treatment must be for induction treatment purposes only; AND  The treatment must be in combination with chemotherapy; AND  The treatment must not exceed 10 doses for induction treatment with this drug for this condition.  A patient may only qualify for PBS-subsidised initiation treatment once in a lifetime under  i) the previously untreated induction treatment restriction; or  ii) the rituximab-refractory re-induction restriction. | Compliance with Authority Required procedures |
| C11826 | P11826 | CN11826 | Infliximab | Moderate to severe ulcerative colitis  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; or  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  Patient must not receive more than 24 weeks of treatment under this restriction; AND  Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or  Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form;  Patient must be aged 18 years or older.  Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.  An application for the continuing treatment must be accompanied with the assessment of response 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.  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.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures |
| C11834 | P11834 | CN11834 | Ixekizumab | Severe psoriatic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C11835 | P11835 | CN11835 | Progesterone | Prevention of preterm birth  Patient must have a singleton pregnancy; AND  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  The treatment must be administered no earlier than at 16 weeks gestation. | Compliance with Authority Required procedures - Streamlined Authority Code 11835 |
| C11836 | P11836 | CN11836 | Sapropterin | Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)  Pre-conception through to when pregnancy first becomes known  Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%; AND  Must be treated by a metabolic physician; or  Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND  Patient must not be undergoing treatment with this drug under this Treatment phase, following completion of this authority application, for more than 13 cumulative months (assuming 1 month consists of 30 days); AND  Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously);  Patient must be actively trying to conceive. | Compliance with Authority Required procedures |
| C11852 | P11852 | CN11852 | Adalimumab | Moderate to severe ulcerative colitis  Initial treatment - Initial 1 (new patient)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND  Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or  Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or  Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND  Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or  Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or  Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years;  Patient must be 6 years of age or older.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes  (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and  (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].  All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.  The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.  A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made 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.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  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.  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  Details of the accepted toxicities including severity can be found on the Services Australia website. | Compliance with Written Authority Required procedures |
| C11853 | P11853 | CN11853 | Adalimumab | Moderate to severe ulcerative colitis  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated 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; or  Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years;  Patient must be 6 years of age or older.  Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Authority Required procedures |
| C11854 | P11854 | CN11854 | Adalimumab | Moderate to severe ulcerative colitis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; or  Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; or  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 more than once if aged 6 to 17 years;  Patient must be 6 years of age or older.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes  (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and  (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C11855 | P11855 | CN11855 | Adalimumab | Moderate to severe ulcerative colitis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or  Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or  Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years;  Patient must be 6 years of age or older.  The authority application must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes  (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and  (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.  All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.  The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.  A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made 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.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  Details of the accepted toxicities including severity can be found on the Services Australia website. | Compliance with Written Authority Required procedures |
| C11861 | P11861 | CN11861 | Adalimumab | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11865 | P11865 | CN11865 | Adalimumab | Severe psoriatic arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11867 | P11867 | CN11867 | Adalimumab | Severe psoriatic arthritis  First continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11875 | P11875 | CN11875 | Sunitinib | Stage IV clear cell variant renal cell carcinoma (RCC)  Continuing treatment beyond 3 months  Patient must have received an initial authority prescription for this drug for this condition; AND  Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND  The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.  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 11875 |
| C11878 | P11878 | CN11878 | Sunitinib | Stage IV clear cell variant renal cell carcinoma (RCC)  Initial treatment  The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND  Patient must have a WHO performance status of 2 or less; AND  The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.  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 11878 |
| C11883 | P11883 | CN11883 | Tofacitinib | Moderate to severe ulcerative colitis  Continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug;  Patient must be aged 18 years or older.  Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures |
| C11886 | P11886 | CN11886 | Tofacitinib  Upadacitinib | Severe psoriatic arthritis  Continuing treatment - balance of supply  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C11890 | P11890 | CN11890 | Guselkumab | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 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.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11903 | P11903 | CN11903 | Adalimumab | Moderate to severe ulcerative colitis  First continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or  Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years;  Patient must be 6 years of age or older.  Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Authority Required procedures |
| C11906 | P11906 | CN11906 | Adalimumab | Severe psoriatic arthritis  Continuing treatment - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
| C11910 | P11910 | CN11910 | Infliximab | Severe Crohn disease  Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; or  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  Patient must not receive more than 24 weeks of treatment under this restriction; AND  Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or  Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND  Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form;  Patient must be aged 18 years or older.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following  (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or  (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  (iii) the date of clinical assessment.  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.  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.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.  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. | Compliance with Written Authority Required procedures |
| C11915 | P11915 | CN11915 | Tofacitinib | Moderate to severe ulcerative colitis  Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle;  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes  (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and  (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.  An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C11917 | P11917 | CN11917 | Guselkumab | Severe psoriatic arthritis  Continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  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.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11918 | P11918 | CN11918 | Guselkumab  Ixekizumab | Severe psoriatic arthritis  Continuing treatment - balance of supply  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C11919 | P11919 | CN11919 | Guselkumab | Severe psoriatic arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND  Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or  Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.  Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and  either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list of major joints  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Written Authority Required procedures |
| C11930 | P11930 | CN11930 | Ipilimumab | Unresectable malignant mesothelioma  Patient must have a WHO performance status of 0 or 1; AND  The treatment must be in combination with PBS-subsidised nivolumab for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition; AND  The treatment must not exceed a maximum total of 24 months in a lifetime for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 11930 |
| C11937 | P11937 | CN11937 | Pazopanib | Stage IV clear cell variant renal cell carcinoma (RCC)  Continuing treatment beyond 3 months  Patient must have received an initial authority prescription for this drug for this condition; AND  Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND  The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.  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 | CN11939 | Pazopanib | Stage IV clear cell variant renal cell carcinoma (RCC)  Continuing treatment beyond 3 months  Patient must have received an initial authority prescription for this drug for this condition; AND  Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND  Patient must require dose adjustment; AND  The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.  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 11939 |
| C11940 | P11940 | CN11940 | Tofacitinib | Moderate to severe ulcerative colitis  Initial treatment - Initial 1 (new patient)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND  Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or  Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or  Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND  Patient must have a Mayo clinic score greater than or equal to 6; or  Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes  (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and  (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].  All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.  If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C11944 | P11944 | CN11944 | Tofacitinib  Upadacitinib | Severe psoriatic arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND  Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or  Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.  Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and  either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list of major joints  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C11945 | P11945 | CN11945 | Tofacitinib  Upadacitinib | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11956 | P11956 | CN11956 | Tofacitinib  Upadacitinib | Severe psoriatic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C11958 | P11958 | CN11958 | Ixekizumab | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11959 | P11959 | CN11959 | Ixekizumab | Severe psoriatic arthritis  Continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11960 | P11960 | CN11960 | Sapropterin | Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)  Existing pregnancy to birth  Patient must be pregnant;  Patient must have demonstrated an adequate response to treatment with this drug at least once in a lifetime, with an adequate response defined as a reduction in phenylalanine levels from baseline during initial responsiveness testing of no less than 30%; AND  Must be treated by a metabolic physician; or  Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND  Patient must not be undergoing further treatment with this drug as a PBS benefit, post-partum in the absence of actively trying to conceive a subsequent child/a known subsequent pregnancy; AND  Patient must not be undergoing simultaneous treatment with this drug under another non-maternal PBS-listing (apply under either listing type, but not both simultaneously). | Compliance with Authority Required procedures |
| C11966 | P11966 | CN11966 | Adalimumab | Moderate to severe ulcerative colitis  Continuing treatment - balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction. | Compliance with Authority Required procedures |
| C11974 | P11974 | CN11974 | Pazopanib | Stage IV clear cell variant renal cell carcinoma (RCC)  Initial treatment  The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND  Patient must have a WHO performance status of 2 or less; AND  The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.  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 |
| C11975 | P11975 | CN11975 | Tofacitinib | Moderate to severe ulcerative colitis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must have a Mayo clinic score greater than or equal to 6; or  Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes  (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and  (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C11976 | P11976 | CN11976 | Tofacitinib  Upadacitinib | Moderate to severe ulcerative colitis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C11978 | P11978 | CN11978 | Tofacitinib  Upadacitinib | Severe psoriatic arthritis  Continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C11979 | P11979 | CN11979 | Guselkumab | Severe psoriatic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Written Authority Required procedures |
| C11981 | P11981 | CN11981 | Ixekizumab | Severe psoriatic arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND  Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or  Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND  Patient must not receive more than 20 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.  Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and  either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list of major joints  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C11985 | P11985 | CN11985 | Nivolumab | Unresectable malignant mesothelioma  Patient must have a WHO performance status of 0 or 1; AND  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  Patient must not have developed disease progression while being treated with this drug for this condition; AND  The treatment must not exceed a maximum total of 24 months in a lifetime for this condition.  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 |
| C12016 | P12016 | CN12016 | Cetuximab | Metastatic colorectal cancer  Continuing treatment  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  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  Patient must not have progressive disease; AND  The treatment must be as monotherapy; or  The treatment must be in combination with chemotherapy; AND  The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.  Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab.  Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab. | Compliance with Authority Required procedures - Streamlined Authority Code 12016 |
| C12029 | P12029 | CN12029 | Eptinezumab  Galcanezumab | Chronic migraine  Continuing treatment  Must be treated by a specialist neurologist or in consultation with a specialist neurologist; AND  Patient must not be undergoing concurrent treatment with the following PBS benefits:   (i) botulinum toxin type A listed for this PBS indication, (ii) another drug in the same pharmacological class as this drug listed for this PBS indication; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month; AND  Patient must continue to be appropriately managed for medication overuse headache.  Patient must have the number of migraine days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12029 |
| C12035 | P12035 | CN12035 | Panitumumab | Metastatic colorectal cancer  Continuing treatment  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  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  Patient must not have progressive disease; AND  The treatment must be as monotherapy; or  The treatment must be in combination with chemotherapy; AND  The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.  Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.  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 |
| C12045 | P12045 | CN12045 | Cetuximab | Metastatic colorectal cancer  Initial treatment  Patient must have RAS wild-type metastatic colorectal cancer; AND  Patient must have a WHO performance status of 2 or less; AND  The condition must have failed to respond to first-line chemotherapy; or  The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC; AND  The treatment must be as monotherapy; or  The treatment must be in combination with chemotherapy; AND  The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.  Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab.  Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab. | Compliance with Authority Required procedures - Streamlined Authority Code 12045 |
| C12049 | P12049 | CN12049 | Infliximab | Moderate to severe ulcerative colitis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or  Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or  Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; or  Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years);  Patient must be 6 years of age or older.  Application for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and  (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.  A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.  All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.  The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.  Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.  A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made 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.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 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.  The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Details of the accepted toxicities including severity can be found on the Services Australia website.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C12051 | P12051 | CN12051 | Infliximab | Severe Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or  Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND  Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or  Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 12051 |
| C12059 | P12059 | CN12059 | Infliximab | Moderate to severe ulcerative colitis  Continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or  Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction; AND  Patient must have demonstrated 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; or  Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years;  Patient must be 6 years of age or older.  Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.  Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response*.*  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.  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.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Authority Required procedures |
| C12066 | P12066 | CN12066 | Panitumumab | Metastatic colorectal cancer  Initial treatment  Patient must have RAS wild-type metastatic colorectal cancer; AND  Patient must have a WHO performance status of 2 or less; AND  The condition must have failed to respond to first-line chemotherapy; or  The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC; AND  The treatment must be as monotherapy; or  The treatment must be in combination with chemotherapy; AND  The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.  Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.  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 12066 |
| C12084 | P12084 | CN12084 | Obeticholic acid | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)  Initial treatment  Must be treated by a prescriber who is either:   (i) a gastroenterologist, (ii) a hepatologist; or  Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND  Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; or  Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated; AND  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  Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug; AND  Patient must not have/be each of:   (i) severe liver disease, (ii) immunocompromised; AND  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  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  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;  Patient must be aged 18 years or older.  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. | Compliance with Authority Required procedures |
| C12096 | P12096 | CN12096 | High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate | Ketogenic diet  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; AND  Patient must have intractable seizures requiring treatment with a ketogenic diet. or  Patient must have a glucose transport protein defect. or  Patient must have pyruvate dehydrogenase deficiency. |  |
| C12098 | P12098 | CN12098 | Adalimumab | Complex refractory Fistulising Crohn disease  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Applications for authorisation must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following  (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and  (ii) details of prior biological medicine treatment including details of date and duration of treatment.  The most recent fistula assessment must be no more than 4 weeks old at the time of application.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C12101 | P12101 | CN12101 | Adalimumab | Complex refractory Fistulising Crohn disease  Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C12103 | P12103 | CN12103 | Adalimumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C12105 | P12105 | CN12105 | Adalimumab | Severe chronic plaque psoriasis  Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | Compliance with Written Authority Required procedures |
| C12120 | P12120 | CN12120 | Adalimumab | Severe active juvenile idiopathic arthritis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply  Must be treated by a paediatric rheumatologist; or  Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C12122 | P12122 | CN12122 | Adalimumab | Severe active juvenile idiopathic arthritis  First continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C12123 | P12123 | CN12123 | Adalimumab | Severe active juvenile idiopathic arthritis  Continuing treatment - balance of supply  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C12138 | P12138 | CN12138 | Obeticholic acid | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)  Continuing treatment  Must be treated by a prescriber who is either:   (i) a gastroenterologist, (ii) a hepatologist; or  Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND  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  Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; or  Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated; AND  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.  The improvement in the qualifying laboratory reading(s) has/have been documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12138 |
| C12140 | P12140 | CN12140 | Obeticholic acid | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)  Transitioning from non-PBS to PBS subsidised supply - Grandfather arrangements  Must be treated by a prescriber who is either:   (i) a gastroenterologist, (ii) a hepatologist; or  Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND  Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; or  Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated; AND  Patient must have received treatment with this drug for this PBS indication prior to 1 September 2021; AND  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  Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug; AND  Patient must not have/be each of:   (i) severe liver disease, (ii) immunocompromised; AND  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  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  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;  Patient must be aged 18 years or older.  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. | Compliance with Authority Required procedures |
| C12147 | P12147 | CN12147 | Adalimumab | Complex refractory Fistulising Crohn disease  Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND  Patient must have an externally draining enterocutaneous or rectovaginal fistula.  Applications for authorisation must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion.  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
| C12148 | P12148 | CN12148 | Adalimumab | Complex refractory Fistulising Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug for this condition.  An adequate response is defined as  (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  Applications for authorisation must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.  The most recent fistula assessment must be no more than 4 weeks old at the time of application.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.  A maximum of 24 weeks treatment will be authorised under this restriction. | Compliance with Written Authority Required procedures |
| C12152 | P12152 | CN12152 | Adalimumab | Complex refractory Fistulising Crohn disease  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Applications for authorisation must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following  (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and  (ii) details of prior biological medicine treatment including details of date and duration of treatment.  The most recent fistula assessment must be no more than 4 weeks old at the time of application.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | Compliance with Written Authority Required procedures |
| C12155 | P12155 | CN12155 | Adalimumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C12156 | P12156 | CN12156 | Adalimumab | Severe chronic plaque psoriasis  Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply  Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C12157 | P12157 | CN12157 | Adalimumab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Whole body  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C12158 | P12158 | CN12158 | Adalimumab | Severe chronic plaque psoriasis  First continuing treatment, Whole body  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C12164 | P12164 | CN12164 | Etanercept | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:   (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; or  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs:   (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; or  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:   (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or  Patient must have a contraindication/severe intolerance to each of:   (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.  The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.  The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.  If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C12174 | P12174 | CN12174 | Adalimumab  Tofacitinib  Upadacitinib | Ankylosing spondylitis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
| C12189 | P12189 | CN12189 | Adalimumab | Severe chronic plaque psoriasis  First continuing treatment, Face, hand, foot  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C12190 | P12190 | CN12190 | Adalimumab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Face, hand, foot  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet and the face, hand, foot area diagrams including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 4 weeks old at the time of application.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C12193 | P12193 | CN12193 | Tocilizumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:   (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; or  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs:   (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; or  Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of:   (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or  Patient must have a contraindication/severe intolerance to each of:   (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.  The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.  The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.  If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.  The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C12194 | P12194 | CN12194 | Adalimumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to 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.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C12212 | P12212 | CN12212 | Adalimumab | Severe chronic plaque psoriasis  Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following  (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and  (ii) details of prior biological treatment, including dosage, date and duration of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C12214 | P12214 | CN12214 | Adalimumab | Severe active juvenile idiopathic arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction. | Compliance with Written Authority Required procedures |
| C12225 | P12225 | CN12225 | Lacosamide | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures  Dose titration at the start of therapy, during therapy or to gradually cease treatment  Must be treated by a neurologist; or  Must be treated by a paediatrician; AND  The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced; AND  The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced; AND  The treatment must be for dose titration purposes. | Compliance with Authority Required procedures - Streamlined Authority Code 12225 |
| C12228 | P12228 | CN12228 | Adalimumab | Complex refractory Fistulising Crohn disease  First continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug for this condition.  An adequate response is defined as  (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  Applications for authorisation must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.  The most recent fistula assessment must be no more than 4 weeks old at the time of application.  An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.  Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.  A maximum of 24 weeks treatment will be authorised under this restriction. | Compliance with Written Authority Required procedures |
| C12229 | P12229 | CN12229 | Adalimumab | Complex refractory Fistulising Crohn disease  Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND  Patient must have an externally draining enterocutaneous or rectovaginal fistula.  Applications for authorisation must be made in writing and must include  (1) two completed authority prescription forms; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.  A maximum of 16 weeks of treatment with this drug will be approved under this criterion.  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
| C12240 | P12240 | CN12240 | Adalimumab | Complex refractory Fistulising Crohn disease  Continuing treatment - balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C12261 | P12261 | CN12261 | Etanercept | Severe chronic plaque psoriasis  Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)  Must be treated by a dermatologist; AND  Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 16 weeks treatment available under any of the initial treatment phases (regardless of the affected body area):   (i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4; AND  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  The treatment must provide no more than the balance of up to 16 weeks treatment. | Compliance with Authority Required procedures |
| C12270 | P12270 | CN12270 | Teriparatide | Severe established osteoporosis  Continuing treatment  Patient must have previously been issued with an authority prescription for this drug; AND  The treatment must not exceed a lifetime maximum of 18 months therapy; AND  Must be treated by a specialist. or  Must be treated by a consultant physician. | Compliance with Authority Required procedures - Streamlined Authority Code 12270 |
| C12271 | P12271 | CN12271 | Durvalumab | Unresectable Stage III non-small cell lung cancer  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  The treatment must not exceed 12 months in total for this condition under the initial and continuing restriction combined; AND  The treatment must be once in a lifetime with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12271 |
| C12285 | P12285 | CN12285 | Ustekinumab | Severe chronic plaque psoriasis  Balance of supply - Continuing treatment (Whole body, or, face/hand/foot)  Must be treated by a dermatologist; AND  Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but the full number of repeats available under the continuing treatment phase was not prescribed. | Compliance with Authority Required procedures |
| C12334 | P12334 | CN12334 | Ustekinumab | Severe chronic plaque psoriasis  Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)  Must be treated by a dermatologist; AND  Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but has received insufficient therapy with this biological medicine to complete 3 doses available under any of the initial treatment phases (regardless of the affected body area):   (i) Initial 1, (ii) Initial 2, (iii) Initial 3; AND  The treatment must be as systemic monotherapy; or  The treatment must be in combination with methotrexate; AND  The treatment must provide no more than the balance of 3 doses available under any of the initial treatment phases. | Compliance with Authority Required procedures |
| C12336 | P12336 | CN12336 | Adalimumab | Moderate to severe hidradenitis suppurativa  Initial treatment - Initial 1 (new patient)  Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND  Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; or  Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; or  Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND  The treatment must be limited to a maximum duration of 16 weeks; AND  Must be treated by a dermatologist.  Assessment of disease severity must be no more than 4 weeks old at the time of application.  An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes  (i) the Hurley stage grading; and  (ii) the AN count; and  (iii) the name of the antibiotic/s received for two separate courses each of three months; or  (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. | Compliance with Authority Required procedures |
| C12349 | P12349 | CN12349 | Beclometasone with formoterol and glycopyrronium  Budesonide with glycopyrronium and formoterol  Fluticasone furoate with umeclidinium and vilanterol | Chronic obstructive pulmonary disease (COPD)  Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; or  Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition; AND  Patient must not be undergoing treatment with this product in each of the following circumstances:   (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information. | Compliance with Authority Required procedures - Streamlined Authority Code 12349 |
| C12351 | P12351 | CN12351 | Leuprorelin  Triptorelin | Central precocious puberty  Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy  Must be treated by a medical practitioner identifying as one of:   (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; or  Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND  Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication. |  |
| C12387 | P12387 | CN12387 | Triptorelin | Central precocious puberty  Initial treatment  Must be treated by a paediatric endocrinologist; or  Must be treated by an endocrinologist specialising in paediatrics;  Patient must be of an age that is prior to their 12th birthday if female; or  Patient must be of an age that is prior to their 13th birthday if male;  Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if female. or  Patient must have had onset of signs/symptoms of central precocious puberty prior to their 10th birthday if male. |  |
| C12392 | P12392 | CN12392 | Certolizumab pegol  Secukinumab | Non-radiographic axial spondyloarthritis  Continuing treatment - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C12399 | P12399 | CN12399 | Tocilizumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND  Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.  If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C12404 | P12404 | CN12404 | Tocilizumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)  Must be treated by a paediatric rheumatologist; or  Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND  Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND  Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab;  Patient must be under 18 years of age.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.  If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.  If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.  An adequate response to treatment is defined as  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C12405 | P12405 | CN12405 | Tocilizumab | Severe active rheumatoid arthritis  Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND  Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  The authority application must be made in writing and must include  (1) a completed authority prescription form; and  (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).  If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.  If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.  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.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| C12435 | P12435 | CN12435 | Lanadelumab | Chronic treatment of hereditary angioedema Types 1 or 2  Continuing preventative treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND  The treatment must not be PBS-subsidised in combination with a C1-esterase inhibitor concentrate; AND  Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist;  Patient must be aged 12 years or older.  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  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 |
| C12440 | P12440 | CN12440 | Ripretinib | Metastatic or unresectable malignant gastrointestinal stromal tumour  Initial treatment  The condition must not be resectable; AND  The treatment must be as monotherapy; AND  The condition must have progressed despite treatment with all drugs PBS-listed specifically for this PBS-indication; or  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  Patient must have a WHO performance status of 2 or less; AND  Patient must be undergoing PBS-subsidised treatment with this drug for the first time - 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. | Compliance with Authority Required procedures |
| C12455 | P12455 | CN12455 | Ripretinib | Metastatic or unresectable malignant gastrointestinal stromal tumour  Continuing treatment  The condition must not be resectable; AND  Patient must have received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be as monotherapy; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C12459 | P12459 | CN12459 | High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate | Ketogenic diet  Patient must have intractable seizures requiring treatment with a ketogenic diet; or  Patient must have a glucose transport protein defect; or  Patient must have pyruvate dehydrogenase deficiency; AND  Patient must have severe intestinal malabsorption of whole protein ketogenic diet formula; AND  Patient must have unsuccessfully trialled at least one of the PBS-listed products with the indication of:   'Ketogenic diet'.  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 |
| C12462 | P12462 | CN12462 | Venetoclax | Acute Myeloid Leukaemia  The condition must be previously untreated at the time of initiation with this drug (except for essential treatment with hydroxyurea or leukapheresis); AND  Patient must not be considered eligible for standard intensive remission induction chemotherapy at the time of initiation with this drug; AND  The treatment must be used in combination with azacitidine (refer to Product Information for timing of azacitidine and venetoclax doses); AND  Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND  The condition must not be acute promyelocytic leukaemia.  Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.  If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles. | Compliance with Authority Required procedures |
| C12464 | P12464 | CN12464 | Lanadelumab | Chronic treatment of hereditary angioedema Types 1 or 2  Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis)  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  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  The treatment must not be used in combination with a C1-esterase inhibitor concentrate; AND  Must be treated by a clinical immunologist or a specialist allergist;  Patient must be aged 12 years or older.  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  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. | Compliance with Authority Required procedures |
| C12467 | P12467 | CN12467 | Lanadelumab | Chronic treatment of hereditary angioedema Types 1 or 2  Initial 2: New patient (commencing from National Blood Authority-funded C1-INH)  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  The treatment must not be used in combination with a C1-esterase inhibitor concentrate; AND  Must be treated by a clinical immunologist or a specialist allergist;  Patient must be aged 12 years or older. | Compliance with Authority Required procedures |
| C12470 | P12470 | CN12470 | Cetuximab | Metastatic colorectal cancer  Continuing treatment  The treatment must be in combination with PBS-subsidised encorafenib for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12470 |
| C12480 | P12480 | CN12480 | Idelalisib | Refractory follicular B-cell non-Hodgkin's lymphoma  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12480 |
| C12483 | P12483 | CN12483 | Cetuximab | Metastatic colorectal cancer  Initial treatment  The treatment must be in combination with PBS-subsidised encorafenib for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12483 |
| C12484 | P12484 | CN12484 | Encorafenib | Metastatic colorectal cancer  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with cetuximab; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12484 |
| C12487 | P12487 | CN12487 | Encorafenib | Metastatic colorectal cancer  Initial treatment  Patient must have BRAF V600 variant positive metastatic colorectal cancer; AND  The treatment must be in combination with cetuximab; AND  Patient must not have received prior treatment with cetuximab for this condition; or  Patient must not have developed disease progression while receiving cetuximab for this condition; AND  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  The condition must have failed to respond to at least one other line of systemic therapy; AND  Patient must have a WHO performance status of 2 or less. | Compliance with Authority Required procedures - Streamlined Authority Code 12487 |
| C12490 | P12490 | CN12490 | Idelalisib | Refractory follicular B-cell non-Hodgkin's lymphoma  Initial treatment  The condition must be refractory to a prior therapy with rituximab within 6 months after completion of treatment with rituximab; AND  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  The treatment must be the sole PBS-subsidised therapy for this condition.  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.  The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.  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 | P12491 | CN12491 | Idelalisib | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for Chronic lymphocytic leukaemia; or  Patient must have previously received PBS-subsidised treatment with this drug for Small lymphocytic leukaemia; AND  Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C12492 | P12492 | CN12492 | Teriparatide | Severe established osteoporosis  Initial treatment  Must be treated by a specialist; or  Must be treated by a consultant physician; AND  Patient must be at very high risk of fracture; AND  Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND  Patient must have had 2 or more fractures due to minimal trauma; AND  Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a lifetime maximum of 18 months therapy; AND  Patient must not have received treatment with PBS-subsidised romosozumab. or  Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.  If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.  If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy*.* Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.  Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.  Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record. | Compliance with Authority Required procedures - Streamlined Authority Code 12492 |
| C12493 | P12493 | CN12493 | Upadacitinib | Chronic severe atopic dermatitis  Continuing or resuming treatment with this drug of the whole body  Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the whole body; AND  Patient must have achieved an adequate response prior to this first continuing treatment authority application; or  Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; or  Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application; AND  Must be treated by a dermatologist; or  Must be treated by a clinical immunologist; AND  Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication:   chronic severe atopic dermatitis).  For the purposes of this restriction, an adequate response to treatment is defined as  (a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and  (b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline  Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.  State each of the current EASI and DLQI scores for this authority application. | Compliance with Authority Required procedures |
| C12494 | P12494 | CN12494 | Upadacitinib | Chronic severe atopic dermatitis  Continuing or resuming treatment with this drug of the face and/or hands  Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the face/hands; AND  Patient must have achieved an adequate response prior to this first continuing treatment authority application; or  Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; or  Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application; AND  Must be treated by a dermatologist; or  Must be treated by a clinical immunologist; AND  Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication:   chronic severe atopic dermatitis).  For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as  (a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or  (ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and  (b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline  Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.  Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes | Compliance with Authority Required procedures |
| C12495 | P12495 | CN12495 | Acalabrutinib  Ibrutinib  Zanubrutinib | Mantle cell lymphoma  Initial treatment  The condition must have relapsed or be refractory to at least one prior therapy; AND  Patient must have a WHO performance status of 0 or 1; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy. or  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 |
| C12497 | P12497 | CN12497 | Dupilumab | Chronic severe atopic dermatitis  Initial treatment of the whole body  Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of:   (i) the whole body, (ii) face/hands; AND  The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND  Patient must not have experienced an inadequate response to this biological medicine in this PBS indication; AND  Must be treated by a dermatologist; or  Must be treated by a clinical immunologist;  Patient must be 12 years of age or older.  State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.  Acceptable scores can be  (a) current scores; or  (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.  The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.  Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records. | Compliance with Authority Required procedures |
| C12499 | P12499 | CN12499 | Upadacitinib | Chronic severe atopic dermatitis  Initial treatment with this drug of the whole body  Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of:   (i) the whole body, (ii) face/hands; AND  Patient must not have experienced an inadequate response to this therapy; AND  Must be treated by a dermatologist; or  Must be treated by a clinical immunologist; AND  Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication:   chronic severe atopic dermatitis);  Patient must be 12 years of age or older.  State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.  Acceptable scores can be  (a) current scores; or  (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.  The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.  Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records. | Compliance with Authority Required procedures |
| C12500 | P12500 | CN12500 | Acalabrutinib  Ibrutinib  Zanubrutinib | Mantle cell lymphoma  Continuing treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures |
| C12504 | P12504 | CN12504 | Upadacitinib | Chronic severe atopic dermatitis  Dose change (increasing up to the 30 mg dose, or, decreasing back down to the 15 mg dose) - whole body, or, face/hands  Patient must not be undergoing each of:   (i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase on more than 2 consecutive occasions; AND  Patient must be undergoing existing PBS-subsidised treatment with this therapy where each of the following is true:   (i) there is a change in daily dose, (ii) any remaining PBS repeat prescriptions for the strength that the patient is changing from, is marked as 'cancelled'; AND  Must be treated by a dermatologist; or  Must be treated by a clinical immunologist; AND  Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication:   chronic severe atopic dermatitis). | Compliance with Authority Required procedures |
| C12507 | P12507 | CN12507 | Dupilumab | Chronic severe atopic dermatitis  Initial treatment of the face and/or hands  The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; or  The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of:   (i) the whole body, (ii) face/hands; AND  The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND  Patient must not have experienced an inadequate response to this biological medicine in this PBS indication; AND  Must be treated by a dermatologist; or  Must be treated by a clinical immunologist;  Patient must be 12 years of age or older.  State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for  (i) erythema,  (ii) oedema/papulation,  (iii) excoriation,  (iv) lichenification  (a) current scores; or  (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.  Acceptable scores can be  (a) current scores; or  (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.  State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.  The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.  Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records. | Compliance with Authority Required procedures |
| C12508 | P12508 | CN12508 | Upadacitinib | Chronic severe atopic dermatitis  Initial treatment with this drug of the face and/or hands  The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; or  The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND  The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of:   (i) the whole body, (ii) face/hands; AND  Patient must not have experienced an inadequate response to this therapy; AND  Must be treated by a dermatologist; or  Must be treated by a clinical immunologist; AND  Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication:   chronic severe atopic dermatitis);  Patient must be 12 years of age or older.  State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for  (i) erythema,  (ii) oedema/papulation,  (iii) excoriation,  (iv) lichenification  (a) current scores; or  (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.  Acceptable scores can be  (a) current scores; or  (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.  State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.  The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.  Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records. | Compliance with Authority Required procedures |
| C12522 | P12522 | CN12522 | Dasatinib  Nilotinib | Chronic Myeloid Leukaemia (CML)  Continuing treatment - third-line therapy  Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition; AND  Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or  Patient must 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  The treatment must be the sole PBS-subsidised therapy for this condition.  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 |
| C12524 | P12524 | CN12524 | Dasatinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - second-line therapy  The condition must be in the chronic phase; or  The condition must be in the accelerated phase; or  The condition must be in the blast phase; AND  Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; AND  Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; or  Patient must have failed an adequate trial of PBS-subsidised first-line treatment with nilotinib for this condition; or  Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition; AND  The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Failure of an adequate trial of imatinib or nilotinib is defined as  (i) Lack of response to initial imatinib or nilotinib therapy, defined as either  (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 nilotinib therapy; OR  (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 nilotinib therapy; OR  (iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  (2) Extramedullary involvement other than spleen and liver; OR  (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 first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.  - failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or  - failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or  - 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 nilotinib; OR  (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 nilotinib therapy; OR  (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 nilotinib therapy; OR  (iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  (2) Extramedullary involvement other than spleen and liver; OR  (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 first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.  Accelerated phase is defined by the presence of 1 or more of the following  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  (2) Extramedullary involvement other than spleen and liver; OR  (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 first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.  Blast crisis is defined as either  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  (2) Extramedullary involvement other than spleen and liver; OR  (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 first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.  Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.  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.  Pathology report(s) confirming a loss of response to imatinib or nilotinib, 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. | Compliance with Authority Required procedures |
| C12525 | P12525 | CN12525 | Imatinib | Chronic Myeloid Leukaemia (CML)  Continuing treatment  Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; AND  The condition must be in the blast phase; AND  The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis. or  The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR). | Compliance with Authority Required procedures - Streamlined Authority Code 12525 |
| C12527 | P12527 | CN12527 | Imatinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - first-line therapy  The condition must be a primary diagnosis of chronic myeloid leukaemia; AND  The condition must be in the accelerated phase; AND  The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or  The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND  Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Accelerated phase is defined by the presence of 1 or more of the following  1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  3. Peripheral basophils greater than or equal to 20%; or  4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).  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.  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. | Compliance with Authority Required procedures |
| C12529 | P12529 | CN12529 | Nilotinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - second-line therapy  The condition must be in the chronic phase; or  The condition must be in the accelerated phase; AND  Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; AND  Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; or  Patient must have failed an adequate trial of PBS-subsidised first-line treatment with dasatinib for this condition; or  Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition; AND  The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Failure of an adequate trial of imatinib or dasatinib is defined as  (i) Lack of response to initial imatinib or dasatinib therapy, defined as either  (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  (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  (iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR  (v) Disease progression (defined as a greater than or equal to.  - 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  - 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  - 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  (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  (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  (iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR  (v) Disease progression (defined as a greater than or equal to.  Accelerated phase is defined by the presence of 1 or more of the following  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR  (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 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.  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.  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.  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. | Compliance with Authority Required procedures |
| C12530 | P12530 | CN12530 | Dasatinib | Chronic Myeloid Leukaemia (CML)  Continuing treatment - second-line therapy  Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; or  Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition; AND  Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or  Patient must 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  The treatment must be the sole PBS-subsidised therapy for this condition.  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 12530 |
| C12531 | P12531 | CN12531 | Methoxsalen | Chronic graft versus host disease  Continuing treatment  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  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; AND  Must be treated by a haematologist; or  Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or  Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND  Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition; AND  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 |
| C12536 | P12536 | CN12536 | Imatinib | Chronic Myeloid Leukaemia (CML)  Continuing treatment - first-line therapy  The condition must be in the chronic phase; AND  Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; or  Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; or  Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition; AND  Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or  Patient must 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  The treatment must be the sole PBS-subsidised therapy for this condition.  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 12536 |
| C12541 | P12541 | CN12541 | Imatinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - first-line therapy  The condition must be a primary diagnosis of chronic myeloid leukaemia; AND  The condition must be in the chronic phase; AND  The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or  The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND  Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; or  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  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  The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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 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.  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.  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. | Compliance with Authority Required procedures |
| C12542 | P12542 | CN12542 | Imatinib | Chronic Myeloid Leukaemia (CML)  Continuing treatment  Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; AND  The condition must be in the accelerated phase; AND  The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis. or  The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR). | Compliance with Authority Required procedures - Streamlined Authority Code 12542 |
| C12543 | P12543 | CN12543 | Imatinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - first-line therapy  The condition must be a primary diagnosis of chronic myeloid leukaemia; AND  The condition must be in the blast phase; AND  The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or  The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND  Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Blast crisis is defined as either  1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  2. Extramedullary involvement other than spleen and liver.  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.  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. | Compliance with Authority Required procedures |
| C12546 | P12546 | CN12546 | Methoxsalen | Chronic graft versus host disease  Initial treatment in a treatment episode  The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; or  The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; or  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; AND  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  Must be treated by a haematologist; or  Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or  Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND  Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation; AND  Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12546 |
| C12549 | P12549 | CN12549 | Nilotinib | Chronic Myeloid Leukaemia (CML)  Grandfather treatment for patients initiated with nilotinib 200 mg prior to 1 April 2012 as first-line therapy  The condition must be in the chronic phase; AND  Patient must have received PBS-subsidised treatment with nilotinib 200mg as a first-line therapy for this condition prior to 1 April 2012; AND  Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or  Patient must 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  The treatment must be the sole PBS-subsidised therapy for this condition.  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 12549 |
| C12557 | P12557 | CN12557 | Nilotinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - first-line therapy  Patient must have a primary diagnosis of chronic myeloid leukaemia; AND  The condition must be in the chronic phase; AND  The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or  The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND  Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; or  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  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  The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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.  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.  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. | Compliance with Authority Required procedures |
| C12559 | P12559 | CN12559 | Gemtuzumab ozogamicin | Acute Myeloid Leukaemia  Induction treatment  Patient must have confirmed CD33-positive AML prior to initiation of treatment; AND  The condition must be de novo; AND  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  Patient must have confirmed intermediate/favourable cytogenetic risk; or  Patient must have unknown cytogenetic risk due to inconclusive test results; AND  Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND  The condition must not be acute promyelocytic leukaemia; AND  The treatment must be in combination with standard intensive remission induction chemotherapy for this condition, which must include cytarabine and an anthracycline; AND  The treatment must not be used in combination with a tyrosine kinase inhibitor; AND  The condition must not be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive; AND  Patient must not receive more than 1 induction cycle under this restriction in a lifetime.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures |
| C12561 | P12561 | CN12561 | Dasatinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - third-line therapy  The condition must be in the chronic phase; or  The condition must be in the accelerated phase; or  The condition must be in the blast phase; AND  Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; or  Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting; AND  Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; AND  Patient must have failed an adequate trial of PBS-subsidised second-line treatment with nilotinib for this condition; AND  The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Failure of an adequate trial of nilotinib is defined as  (i) Lack of response to second line nilotinib therapy, defined as either  (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 nilotinib therapy; OR  (iv) Development of accelerated phase or blast crisis in a patient previously prescribed nilotinib for any phase of chronic myeloid leukaemia.  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  (2) Extramedullary involvement other than spleen and liver; OR  (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 nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.  - failure to achieve a haematological response after a minimum of 3 months therapy with nilotinib for patients initially treated in chronic phase; or  - failure to achieve any cytogenetic response after a minimum of 6 months therapy with nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or  - 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 nilotinib; OR  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 nilotinib therapy; OR  (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 nilotinib therapy; OR  (iv) Development of accelerated phase or blast crisis in a patient previously prescribed nilotinib for any phase of chronic myeloid leukaemia.  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  (2) Extramedullary involvement other than spleen and liver; OR  (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 nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.  Accelerated phase is defined by the presence of 1 or more of the following  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  (2) Extramedullary involvement other than spleen and liver; OR  (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 nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.  Blast crisis is defined as either  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or  (2) Extramedullary involvement other than spleen and liver; OR  (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 nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.  Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.  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.  Pathology report(s) confirming a loss of response to imatinib and nilotinib, 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. | Compliance with Authority Required procedures |
| C12563 | P12563 | CN12563 | Nilotinib | Chronic Myeloid Leukaemia (CML)  Continuing treatment - second-line therapy  Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; or  Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition; AND  Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or  Patient must 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  The treatment must be the sole PBS-subsidised therapy for this condition.  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 |
| C12565 | P12565 | CN12565 | Dasatinib | Chronic Myeloid Leukaemia (CML)  Continuing treatment - first-line therapy  The condition must be in the chronic phase; AND  Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; or  Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; or  Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition; AND  Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or  Patient must 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  The treatment must be the sole PBS-subsidised therapy for this condition.  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 12565 |
| C12566 | P12566 | CN12566 | Gemtuzumab ozogamicin | Acute Myeloid Leukaemia  Consolidation treatment  Patient must have achieved a complete remission following induction treatment with this drug for this condition; AND  The treatment must be in combination with standard intensive remission consolidation chemotherapy for this condition, which must include cytarabine and an anthracycline; AND  Patient must not receive more than 2 consolidation cycles under this restriction in a lifetime.  This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.  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 109 cells/L with a platelet count of 100 x 109/L or more in the peripheral blood in the absence of transfusion.  Progressive disease is defined as the presence of any of the following  a) Leukaemic cells in the CSF;  b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;  c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;  d) Extramedullary leukaemia. | Compliance with Authority Required procedures |
| C12567 | P12567 | CN12567 | Methoxsalen | Chronic graft versus host disease  Continuing treatment  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  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; AND  Must be treated by a haematologist; or  Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or  Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND  Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition; AND  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 |
| C12569 | P12569 | CN12569 | Nilotinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - third-line therapy  The condition must be in the chronic phase; or  The condition must be in the accelerated phase; AND  Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; or  Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting; AND  Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; AND  Patient must have failed an adequate trial of PBS-subsidised second-line treatment with dasatinib for this condition; AND  The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Failure of an adequate trial of dasatinib is defined as:  (i) Lack of response to second-line dasatinib therapy, defined as either:  (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  (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  (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:  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR  (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.  - failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib for patients initially treated in chronic phase; or  - 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  - 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  (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  (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  (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:  (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or  (2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or  (3) Peripheral basophils greater than or equal to 20%; or  (4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or  (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR  (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.  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.  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.  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. | Compliance with Authority Required procedures |
| C12570 | P12570 | CN12570 | Dasatinib | Chronic Myeloid Leukaemia (CML)  Initial treatment - first-line therapy  Patient must have a primary diagnosis of chronic myeloid leukaemia; AND  The condition must be in the chronic phase; AND  The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or  The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND  Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; or  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  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  The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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 dasatinib of 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.  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.  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. | Compliance with Authority Required procedures |
| C12572 | P12572 | CN12572 | Nilotinib | Chronic Myeloid Leukaemia (CML)  Continuing treatment - first-line therapy  The condition must be in the chronic phase; AND  Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; or  Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; or  Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; AND  Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or  Patient must 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  The treatment must be the sole PBS-subsidised therapy for this condition.  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 |
| C12579 | P12579 | CN12579 | Methoxsalen | Chronic graft versus host disease  Initial treatment in a treatment episode  The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; or  The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; or  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; AND  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  Must be treated by a haematologist; or  Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or  Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND  Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation; AND  Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12579 |
| C12585 | P12585 | CN12585 | Siltuximab | Idiopathic multicentric Castleman disease (iMCD)  Initial treatment  Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records; AND  The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD:   (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder; AND  Must be treated by a haematologist; or  Must be treated by a medical physician working under the supervision of a haematologist; AND  Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed. or  Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription.  Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum. | Compliance with Authority Required procedures |
| C12590 | P12590 | CN12590 | Olaparib | Castration resistant metastatic carcinoma of the prostate  Initial treatment  The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND  The treatment must not be subsidised in combination with:   (i) chemotherapy, (ii) a novel hormonal drug; AND  The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease); AND  Patient must have a WHO performance status of 2 or less; AND  Patient must be undergoing treatment with this drug for the first time. | Compliance with Authority Required procedures |
| C12594 | P12594 | CN12594 | Siltuximab | Idiopathic multicentric Castleman disease (iMCD)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND  Must be treated by a haematologist. or  Must be treated by a medical physician working under the supervision of a haematologist.  Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum. | Compliance with Authority Required procedures |
| C12598 | P12598 | CN12598 | Olaparib | Castration resistant metastatic carcinoma of the prostate  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND  The treatment must not be subsidised in combination with:   (i) chemotherapy, (ii) a novel hormonal drug. | Compliance with Authority Required procedures |
| C12599 | P12599 | CN12599 | Tiotropium | Severe asthma  Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of:   (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique; AND  The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated;  Patient must be at least 18 years of age.  Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist. |  |
| C12603 | P12603 | CN12603 | Beclometasone with formoterol and glycopyrronium  Fluticasone furoate with umeclidinium and vilanterol  Indacaterol with glycopyrronium and mometasone | Severe asthma  Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of:   (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique;  Patient must be at least 18 years of age.  Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist. | Compliance with Authority Required procedures - Streamlined Authority Code 12603 |
| C12604 | P12604 | CN12604 | Ivermectin | Human sarcoptic scabies  The condition must be established by clinical and/or parasitological examination;  Patient must identify as Aboriginal or Torres Strait Islander;  Patient must weigh 15 kg or over;  Patient must be 5 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 12604 |
| C12607 | P12607 | CN12607 | Budesonide | Mild to moderate Crohn disease  The condition must affect the ileum. or  The condition must affect the ascending colon. or  The condition must affect the ileum and ascending colon.  The total duration of therapy should be no more than 12 weeks in any single course. | Compliance with Authority Required procedures - Streamlined Authority Code 12607 |
| C12619 | P12619 | CN12619 | Cabotegravir | HIV infection  Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND  The treatment must be in combination with rilpivirine tablets; AND  Patient must intend to proceed to treatment with intramuscular administration of cabotegravir and rilpivirine. | Compliance with Authority Required procedures - Streamlined Authority Code 12619 |
| C12636 | P12636 | CN12636 | Cabotegravir and rilpivirine | HIV infection  Patient must have previously received PBS-subsidised therapy for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12636 |
| C12656 | P12656 | CN12656 | Sacituzumab govitecan | Unresectable locally advanced or metastatic triple-negative breast cancer  Initial treatment  Patient must have progressive disease following two or more prior systemic therapies, at least one of them in the locally advanced or metastatic setting; AND  The condition must be inoperable; AND  Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND  The treatment must be the sole PBS-subsidised therapy for this PBS indication. | Compliance with Authority Required procedures - Streamlined Authority Code 12656 |
| C12669 | P12669 | CN12669 | Sacituzumab govitecan | Unresectable locally advanced or metastatic triple-negative breast cancer  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this PBS indication. | Compliance with Authority Required procedures - Streamlined Authority Code 12669 |
| C12685 | P12685 | CN12685 | Imatinib | Malignant gastrointestinal stromal tumour  Initial treatment  The condition must be metastatic; or  The condition must be unresectable; AND  The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining; AND  The condition must have not achieved a response with this drug at a dose of 400 mg per day; AND  The treatment must not exceed 3 months under this restriction.  Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.  Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.  A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347 472-80.)  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.  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.  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. | Compliance with Authority Required procedures |
| C12691 | P12691 | CN12691 | Daratumumab | Relapsed and/or refractory multiple myeloma  Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |
| C12694 | P12694 | CN12694 | Carfilzomib | Multiple myeloma  Initial treatment - once weekly treatment regimen  The condition must be confirmed by a histological diagnosis; AND  The treatment must be in combination with dexamethasone; AND  Patient must have progressive disease after at least one prior therapy; AND  Patient must have undergone or be ineligible for a stem cell transplant; AND  Patient must not have previously received this drug for this condition; AND  Patient must not receive more than three cycles of treatment under this restriction.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures - Streamlined Authority Code 12694 |
| C12703 | P12703 | CN12703 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more. or  Patient must be female and must not have a bone age of 13.5 years or more.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12704 | P12704 | CN12704 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Initial treatment  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; or  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND  Patient must have a current height at or below the 1st percentile for age and sex; AND  Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; or  Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND  6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12705 | P12705 | CN12705 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome  Initial treatment  Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); or  Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND  Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; or  Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; or  Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment; AND  Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must not have a chronological age of 18 years or greater; AND  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. A minimum of 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND  4. The date at which skeletal maturity was achieved (if applicable) [Note In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND  5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR  (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist  6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with 1 repeat allowed)  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12711 | P12711 | CN12711 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a chronological age of 5 years or greater; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12712 | P12712 | CN12712 | Somatropin | Short stature associated with Turner syndrome  Recommencement of treatment as a reclassified patient  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a height greater than or equal to 155.0 cm; AND  Patient must not have a bone age of 13.5 years or greater.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. A height measurement from immediately prior to commencement of growth hormone treatment; AND  4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND  5. Recent growth data (height and weight, not older than three months); AND  6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12713 | P12713 | CN12713 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Initial treatment  Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; or  Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; or  Patient must be female and menarche occurred before the chronological age of 10 years; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months; AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. Confirmation that the patient has precocious puberty; AND  7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12721 | P12721 | CN12721 | Somatropin | Short stature associated with chronic renal insufficiency  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND  5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  6. Recent growth data (height and weight, not older than three months); AND  7. A bone age result performed within the last 12 months; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12722 | P12722 | CN12722 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Initial treatment  Patient must have had an intracranial lesion which is under appropriate observation and management; or  Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have a current height at or below the 1st percentile for age and sex; or  Patient must have a current height above the 1st percentile for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have a current height above the 1st percentile for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; or  Patient must have a current height above the 1st percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12723 | P12723 | CN12723 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Initial treatment  Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; or  Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; or  Patient must be female and menarche occurred before the chronological age of 10 years; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. Confirmation that the patient has precocious puberty; AND  7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12725 | P12725 | CN12725 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12726 | P12726 | CN12726 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have had an intracranial lesion which is under appropriate observation and management; or  Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND  6. Recent growth data (height and weight, not older than three months); AND  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12731 | P12731 | CN12731 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more. or  Patient must be female and must not have a bone age of 13.5 years or more.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12738 | P12738 | CN12738 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; or  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND  4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND  5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND  6. Recent growth data (height and weight, not older than three months); AND  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12749 | P12749 | CN12749 | Somatropin | Short stature associated with chronic renal insufficiency  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2 ; AND  5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  7. A bone age result performed within the last 12 months; AND  The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12752 | P12752 | CN12752 | Somatropin | Short stature associated with chronic renal insufficiency  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND  Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;  Patient must be aged 3 years or older.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months; AND  5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND  6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12755 | P12755 | CN12755 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Initial treatment  Patient must have had an intracranial lesion which is under appropriate observation and management; or  Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have a current height at or below the 1st percentile for age and sex; or  Patient must have a current height above the 1st percentile for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have a current height above the 1st percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND  4. A bone age result performed within the last 12 months; AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12758 | P12758 | CN12758 | Somatropin | Short stature associated with Turner syndrome  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a bone age of 13.5 years or greater; AND  Patient must not have a height greater than or equal to 155.0 cm; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. A height measurement from immediately prior to commencement of growth hormone treatment; AND  4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND  5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12760 | P12760 | CN12760 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; or  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12765 | P12765 | CN12765 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Initial treatment  Patient must have a structural lesion that is not neoplastic; or  Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); or  Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND  Patient must have hypothalamic obesity; AND  Patient must have a growth velocity above the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have an annual growth velocity of greater than 14 cm per year if the patient has a chronological age of 2 years or less; or  Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND  8. Confirmation that the patient has hypothalamic obesity; AND  9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12768 | P12768 | CN12768 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category; AND  Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed; AND  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies; or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved height percentile for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies; or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved waist circumference while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies; or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must not have been on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies; or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved waist circumference while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies; or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height;  Patient must not have a chronological age of equal to or greater than 18 years.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height, weight and waist circumference) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. The date at which skeletal maturity was achieved (if applicable) [Note In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND  5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12769 | P12769 | CN12769 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have had an intracranial lesion which is under appropriate observation and management; or  Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  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.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12770 | P12770 | CN12770 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have a structural lesion that is not neoplastic; or  Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); or  Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND  Patient must have hypothalamic obesity; AND  Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND  7. Confirmation that the patient has hypothalamic obesity; AND  8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12771 | P12771 | CN12771 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; or  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND  4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND  5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12774 | P12774 | CN12774 | Somatropin | Short stature associated with Turner syndrome  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be female and must not have a bone age of 13.5 years or more; AND  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12775 | P12775 | CN12775 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have a chronological age of less than 2 years; AND  Patient must have a documented clinical risk of hypoglycaemia; AND  Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND  4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND  5. Recent growth data (height and weight, not older than three months); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12779 | P12779 | CN12779 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more. or  Patient must be female and must not have a bone age of 13.5 years or more.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12780 | P12780 | CN12780 | Somatropin | Short stature associated with Turner syndrome  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND  Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a bone age of 13.5 years or greater; AND  Patient must not have a height greater than or equal to 155.0 cm.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12784 | P12784 | CN12784 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12785 | P12785 | CN12785 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have a structural lesion that is not neoplastic; or  Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); or  Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND  Patient must have hypothalamic obesity; AND  Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND  7. Confirmation that the patient has hypothalamic obesity; AND  8. Recent growth data (height and weight, not older than three months); AND  9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12789 | P12789 | CN12789 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have a structural lesion that is not neoplastic; or  Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); or  Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND  Patient must have hypothalamic obesity; AND  Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND  7. Confirmation that the patient has hypothalamic obesity; AND  8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  9. A bone age result performed within the last 12 months; AND  10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12790 | P12790 | CN12790 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; or  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND  4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND  5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  7. A bone age result performed within the last 12 months; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12791 | P12791 | CN12791 | Somatropin | Short stature associated with chronic renal insufficiency  Initial treatment  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND  Patient must have a current height at or below the 1st percentile for age and sex; or  Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; or  Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND  6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12793 | P12793 | CN12793 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader Willi syndrome category; AND  Patient must have had a lapse in growth hormone treatment; AND  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by an adverse reaction to growth hormone; AND  Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems; or  Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height;  Patient must not have a chronological age of equal to or greater than 18 years;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height, weight, and waist circumference, not older than three months); AND  4. The date at which skeletal maturity was achieved (if applicable) [Note In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND  5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12798 | P12798 | CN12798 | Somatropin | Short stature associated with chronic renal insufficiency  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND  5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  6. Recent growth data (height and weight, not older than three months); AND  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12803 | P12803 | CN12803 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants  Initial treatment  Must be treated by a specialist or consultant physician in paediatric endocrinology; or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND  Patient must have a chronological age of less than 2 years; AND  Patient must have a documented clinical risk of hypoglycaemia; AND  Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND  5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12805 | P12805 | CN12805 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a chronological age of 5 years or greater;  Patient must be aged 3 years or older.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months; AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12806 | P12806 | CN12806 | Somatropin | Short stature associated with chronic renal insufficiency  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND  Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND  Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; AND  Patient must be male and must not have a height greater than or equal to 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months; AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12809 | P12809 | CN12809 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a chronological age of 5 years or greater; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;  Patient must be aged 3 years or older.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months; AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12810 | P12810 | CN12810 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have had an intracranial lesion which is under appropriate observation and management; or  Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND  6. Recent growth data (height and weight, not older than three months); AND  7. A bone age result performed within the last 12 months; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12812 | P12812 | CN12812 | Somatropin | Short stature associated with chronic renal insufficiency  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2 ; AND  5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12817 | P12817 | CN12817 | Somatropin | Short stature associated with Turner syndrome  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a bone age of 13.5 years or greater; AND  Patient must not have a height greater than or equal to 155.0 cm;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. A height measurement from immediately prior to commencement of growth hormone treatment; AND  4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND  5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12820 | P12820 | CN12820 | Somatropin | Short stature associated with Turner syndrome  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be female and must not have a bone age of 13.5 years or more; AND  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;  Patient must be aged 3 years or older.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12821 | P12821 | CN12821 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have a structural lesion that is not neoplastic; or  Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); or  Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND  Patient must have hypothalamic obesity; AND  Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND  7. Confirmation that the patient has hypothalamic obesity; AND  8. Recent growth data (height and weight, not older than three months); AND  9. A bone age result performed within the last 12 months; AND  10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Authority Required procedures |
| C12824 | P12824 | CN12824 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; or  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months; AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12826 | P12826 | CN12826 | Somatropin | Short stature associated with Turner syndrome  Initial treatment  Must be treated by a specialist or consultant physician in paediatric endocrinology; or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must not have a height greater than or equal to 155.0 cm; AND  Patient must not have a bone age of 13.5 years or greater;  Patient must be aged 3 years or older.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12829 | P12829 | CN12829 | Somatropin | Short stature associated with chronic renal insufficiency  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND  Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND  6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12831 | P12831 | CN12831 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a chronological age of 5 years or greater.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12832 | P12832 | CN12832 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have a chronological age of less than 2 years; AND  Patient must have a documented clinical risk of hypoglycaemia; AND  Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND  4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND  5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12834 | P12834 | CN12834 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category; AND  Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; AND  Patient must be male and must not have a bone age of 15.5 years or more. or  Patient must be female and must not have a bone age of 13.5 years or more.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12842 | P12842 | CN12842 | Daratumumab | Relapsed and/or refractory multiple myeloma  Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements  Patient must have been on treatment with this drug in the subcutaneous form for this condition prior to 1 November 2021; AND  Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are:   (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.  Details of the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.  Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records  (a) the level of serum monoclonal protein; or  (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or  (c) the serum level of free kappa and lambda light chains; or  (d) bone marrow aspirate or trephine; or  (e) if present, the size and location of lytic bone lesions (not including compression fractures); or  (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or  (g) if present, the level of hypercalcaemia, corrected for albumin concentration.  As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.  A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.  A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease. | Compliance with Authority Required procedures |
| C12845 | P12845 | CN12845 | Daratumumab | Relapsed and/or refractory multiple myeloma  Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with bortezomib and dexamethasone; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |
| C12847 | P12847 | CN12847 | Elotuzumab | Relapsed and/or refractory multiple myeloma  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with lenalidomide and dexamethasone; AND  Patient must not have developed disease progression while receiving treatment with this drug for this condition.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures |
| C12849 | P12849 | CN12849 | Carfilzomib | Multiple myeloma  Continuing treatment - once weekly treatment regimen  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with dexamethasone; AND  Patient must not develop disease progression while receiving treatment with this drug for this condition; AND  Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures - Streamlined Authority Code 12849 |
| C12855 | P12855 | CN12855 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Initial treatment  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; or  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND  Patient must have a current height at or below the 1st percentile for age and sex; AND  Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND  4. A bone age result performed within the last 12 months; AND  5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND  6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12857 | P12857 | CN12857 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders; AND  Patient must have had a lapse in treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; or  Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND  4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND  5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND  6. Recent growth data (height and weight, not older than three months); AND  7. A bone age result performed within the last 12 months; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12858 | P12858 | CN12858 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; or  Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; or  Patient must be female and menarche occurred before the chronological age of 10 years; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. Confirmation that the patient has precocious puberty; AND  4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12860 | P12860 | CN12860 | Somatropin | Short stature associated with Turner syndrome  Initial treatment  Must be treated by a specialist or consultant physician in paediatric endocrinology; or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must not have a height greater than or equal to 155.0cm; AND  Patient must not have a bone age of 13.5 years or greater.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  (b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12861 | P12861 | CN12861 | Somatropin | Short stature associated with chronic renal insufficiency  Initial treatment  Must be treated by a specialist or consultant physician in paediatric endocrinology; or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND  Patient must have a current height at or below the 1st percentile for age and sex; or  Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a height greater than or equal to 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND  4. A bone age result performed within the last 12 months; AND  5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND  6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12866 | P12866 | CN12866 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12867 | P12867 | CN12867 | Somatropin | Short stature associated with chronic renal insufficiency  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND  Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2; AND  Patient must be male and must not have a height greater than or equal to 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; AND  Patient must be male and must not have a bone age of 15.5 years or more. or  Patient must be female and must not have a bone age of 13.5 years or more.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12869 | P12869 | CN12869 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); or  Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND  Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; or  Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; or  Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; or  Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment; AND  Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a chronological age of 18 years or greater; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR  (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND  4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment or within the last 12 months, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND  5. Recent growth data (height and weight, not older than three months); AND  6. The date at which skeletal maturity was achieved (if applicable) [Note In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12871 | P12871 | CN12871 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months; AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12872 | P12872 | CN12872 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category; AND  Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis); AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a height greater than or equal to 167.7 cm; or  Patient must be female and must not have a height greater than or equal to 155.0 cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months; AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12876 | P12876 | CN12876 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;  Patient must be aged 3 years or older.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months; AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12877 | P12877 | CN12877 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; or  Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; or  Patient must be female and menarche occurred before the chronological age of 10 years; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. Confirmation that the patient has precocious puberty; AND  4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. Recent growth data (height and weight, not older than three months); AND  7. A bone age result performed within the last 12 months; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12880 | P12880 | CN12880 | Somatropin | Short stature associated with Turner syndrome  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND  Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a bone age of 13.5 years or greater; AND  Patient must not have a height greater than or equal to 155.0 cm;  Patient must be aged 3 years or older.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12882 | P12882 | CN12882 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;  Patient must be aged 3 years or older.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months; AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12884 | P12884 | CN12884 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; or  Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; or  Patient must be female and menarche occurred before the chronological age of 10 years; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. Confirmation that the patient has precocious puberty; AND  4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. Recent growth data (height and weight, not older than three months); AND  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12886 | P12886 | CN12886 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; or  Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; or  Patient must be female and menarche occurred before the chronological age of 10 years; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. Confirmation that the patient has precocious puberty; AND  4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  7. A bone age result performed within the last 12 months; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12887 | P12887 | CN12887 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); or  Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND  Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; AND  Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a chronological age of 18 years or greater; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR  (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND  4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND  5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  6. The date at which skeletal maturity was achieved (if applicable) [Note In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12895 | P12895 | CN12895 | Apalutamide  Darolutamide  Enzalutamide | Castration resistant non-metastatic carcinoma of the prostate  The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition; AND  The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug; AND  Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND  Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND  Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); or  Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation; AND  Patient must be undergoing concurrent treatment with androgen deprivation therapy.  Prescribing instructions  Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application.  The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading. | Compliance with Authority Required procedures |
| C12899 | P12899 | CN12899 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months; AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Written Authority Required procedures |
| C12901 | P12901 | CN12901 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Recommencement of treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;  Patient must be aged 3 years or older.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND  3. Recent growth data (height and weight, not older than three months); AND  4. A bone age result performed within the last 12 months; AND  5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Authority Required procedures |
| C12916 | P12916 | CN12916 | Somatropin | Short stature associated with Turner syndrome  Recommencement of treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature assciated with Turner syndrome; AND  Patient must have had a lapse in growth hormone treatment; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; or  Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have a height greater than or equal to 155.0 cm; AND  Patient must not have a bone age of 13.5 years or greater; AND  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;  Patient must be aged 3 years or older.  The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND  3. A height measurement from immediately prior to commencement of growth hormone treatment; AND  4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND  5. Recent growth data (height and weight, not older than three months); AND  6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Authority Required procedures |
| C12918 | P12918 | CN12918 | Somatropin | Biochemical growth hormone deficiency and precocious puberty  Continuing treatment  Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category; AND  Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND  3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  4. A bone age result performed within the last 12 months; AND  5. The final adult height (in cm) of the patient's mother and father (where available); AND  6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Authority Required procedures |
| C12926 | P12926 | CN12926 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth  Initial treatment  Must be treated by a specialist or consultant physician in paediatric endocrinology; or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology; AND  Patient must have a structural lesion that is not neoplastic; or  Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); or  Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND  Patient must have hypothalamic obesity; AND  Patient must have a growth velocity above the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND  4. A bone age result performed within the last 12 months; AND  5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  (b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  (c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND  7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND  8. Confirmation that the patient has hypothalamic obesity; AND  9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Authority Required procedures |
| C12928 | P12928 | CN12928 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation  Continuing treatment as a reclassified patient  Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation; AND  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or  The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND  Patient must have had an intracranial lesion which is under appropriate observation and management; or  Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or  Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND  Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; or  Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more;  Patient must be aged 3 years or older;  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or  Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND  3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND  4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND  5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND  7. A bone age result performed within the last 12 months; AND  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Authority Required procedures |
| C12929 | P12929 | CN12929 | Somatropin | Short stature associated with chronic renal insufficiency  Initial treatment  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or  Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant; AND  Patient must have a current height at or below the 1st percentile for age and sex; or  Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or  Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; or  Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less; AND  Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND  Patient must not have an active tumour or evidence of tumour growth or activity; AND  Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND  Patient must be male and must not have a height greater than or equal to 167.7cm; or  Patient must be female and must not have a height greater than or equal to 155.0cm; AND  Patient must be male and must not have a bone age of 15.5 years or more; or  Patient must be female and must not have a bone age of 13.5 years or more; AND  Must be treated by a specialist or consultant physician in paediatric endocrinology. or  Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.  An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.  The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program) Special Arrangement 2015* and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  The authority application must be in writing and must include  1. A completed authority prescription form; AND  2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND  3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND  4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND  5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND  6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND  7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).  Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.  In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy. | Compliance with Authority Required procedures |
| C12930 | P12930 | CN12930 | Carfilzomib | Multiple myeloma  Continuing treatment - twice weekly treatment regimen  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with dexamethasone; AND  Patient must not develop disease progression while receiving treatment with this drug for this condition; AND  Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures - Streamlined Authority Code 12930 |
| C12934 | P12934 | CN12934 | Carfilzomib | Multiple myeloma  Initial treatment - twice weekly treatment regimen  The condition must be confirmed by a histological diagnosis; AND  The treatment must be in combination with dexamethasone; AND  Patient must have progressive disease after at least one prior therapy; AND  Patient must have undergone or be ineligible for a stem cell transplant; AND  Patient must not have previously received this drug for this condition; AND  Patient must not receive more than three cycles of treatment under this restriction.  Progressive disease is defined as at least 1 of the following  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | Compliance with Authority Required procedures - Streamlined Authority Code 12934 |
| C12976 | P12976 | CN12976 | Tofacitinib | Moderate to severe ulcerative colitis  Continuing treatment - balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C12979 | P12979 | CN12979 | Amifampridine | Lambert-Eaton myasthenic syndrome (LEMS)  The condition must not be any of:   (i) myasthenia gravis, (ii) Guillain-Barre syndrome; AND  Must be treated by a prescriber type identifying as at least one of the following:   (i) a clinical immunologist, (ii) a neurologist, (iii) a medical practitioner working under the direct supervision of one of these mentioned specialists. | Compliance with Authority Required procedures |
| C12981 | P12981 | CN12981 | Larotrectinib | Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion  Initial treatment  The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence:   (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date; AND  The condition must be a mammary analogue secretory carcinoma of the salivary gland confirmed through a pathology report from an Approved Pathology Authority (of any date); or  The condition must be a secretory breast carcinoma confirmed through a pathology report from an Approved Pathology Authority (of any date); AND  The condition must be metastatic disease; or  The condition must be both:   (i) locally advanced, (ii) unresectable; or  The condition must be both:   (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition;  Patient must be at least 18 years of age.  The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include  (a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.  (b) details of the pathology report establishing the carcinoma type (salivary gland/secretory breast carcinoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.  All reports must be documented in the patient's medical records.  If the application is submitted through HPOS upload or mail, it must include  (a) a completed authority prescription form; and  (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Authority Required procedures |
| C12982 | P12982 | CN12982 | Larotrectinib | 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  Initial treatment  The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence:   (i) the date of the pathology report substantiating the positive NTRK gene fusion, (ii) the name of the pathology service provider, (iii) the unique identifying number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date; AND  The condition must be metastatic disease; or  The condition must be both:   (i) locally advanced, (ii) unresectable; or  The condition must be both:   (i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection; AND  The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND  Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition;  Patient must be/have been under 18 years of age (i.e. prior to their 18th birthday) at treatment initiation with this drug.  The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include  (a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.  All reports must be documented in the patient's medical records.  If the application is submitted through HPOS upload or mail, it must include  (a) a completed authority prescription form; and  (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Authority Required procedures |
| C12999 | P12999 | CN12999 | Zanubrutinib | Waldenstrom macroglobulinaemia  Continuing treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |