**PB 26 of 2024**

# National Health (Listing of Pharmaceutical Benefits) Instrument 2024

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

*National Health Act 1953*

This Instrument is in 8 volumes

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

Each volume has its own contents

# Contents

# Schedule 4—Circumstances, purposes, conditions and variations

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

# Part 1—Circumstances, purposes and conditions

## 1 Circumstances, purposes and conditions

The following table sets out:

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

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

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

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|---|---|---|---|---|---|
| C10020 | P10020 | CN10020 | Risperidone | Behavioural disturbances<br>Initial treatment<br>The condition must be characterised by psychotic symptoms and aggression; AND<br>Patient must have dementia of the Alzheimer type; AND<br>Patient must have failed to respond to non-pharmacological methods of treatment; AND<br>Patient must not receive more than 12 weeks of treatment under this restriction.<br>A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period. | Compliance with Authority Required procedures - Streamlined Authority Code 10020 |
| C10021 | P10021 | CN10021 | Risperidone | Behavioural disturbances<br>Continuing treatment, trial of dose reduction or cessation of treatment<br>The condition must be characterised by psychotic symptoms and aggression; AND<br>Patient must have dementia of the Alzheimer type; AND | Compliance with Authority Required procedures |

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| | | | | Patient must have responded to an initial course of treatment with this drug for this condition; AND<br>Patient must have failed to respond to non-pharmacological methods of treatment; AND<br>The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; or<br>Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically; AND<br>Patient must be optimised on non-pharmacological methods of treatment.<br>The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving a least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.<br>Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.<br>Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.<br>Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.<br>Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.<br>Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records. | |
| C10023 | P10023 | CN10023 | Avelumab | Stage IV (metastatic) Merkel Cell Carcinoma<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 10023 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction. | |
| C10033 | P10033 | CN10033 | Cobimetinib | Unresectable Stage III or Stage IV malignant melanoma<br>Initial treatment<br>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<br>Initial treatment<br>Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10051 |
| C10061 | P10061 | CN10061 | Lanreotide<br>Octreotide | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition;<br>Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.<br>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Compliance with Authority Required procedures - Streamlined Authority Code 10061 |
| C10063 | P10063 | CN10063 | Cinacalcet | Secondary hyperparathyroidism<br>Continuing treatment<br>Must be treated by a nephrologist; AND<br>Patient must have chronic kidney disease; AND<br>Patient must be on dialysis; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10063 |

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| | | | | 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.<br>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. | |
| C10067 | P10067 | CN10067 | Cinacalcet | Secondary hyperparathyroidism<br>Continuing treatment<br>Must be treated by a nephrologist; AND<br>Patient must have chronic kidney disease; AND<br>Patient must be on dialysis; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition.<br>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.<br>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<br>Continuing treatment<br>Patient must have chronic kidney disease; AND<br>Patient must be on dialysis; AND<br>Patient must have achieved a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment. or<br>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.<br>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. | Compliance with Authority Required procedures - Streamlined Authority Code 10068 |

Clause 1

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| | | | | 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. | |
| C10073 | P10073 | CN10073 | Cinacalcet | Secondary hyperparathyroidism<br>Initial treatment<br>Must be treated by a nephrologist; AND<br>Patient must have chronic kidney disease; AND<br>Patient must be on dialysis; AND<br>Patient must have failed to respond to conventional therapy; AND<br>Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L. or<br>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.<br>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.<br>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 | Lanreotide<br>Octreotide | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition;<br>Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2. | Compliance with Authority Required procedures - Streamlined Authority Code 10075 |

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| | | | | WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | |
| C10076 | P10076 | CN10076 | Sapropterin | Hyperphenylalaninaemia<br>Initial treatment<br>Must be treated by a metabolic physician; AND<br>Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.<br>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<br>Octreotide | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)<br>The condition must be unresectable locally advanced disease or metastatic disease; AND<br>The condition must be World Health Organisation (WHO) grade 1 or 2; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition;<br>Patient must be aged 18 years or older.<br>WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.<br>WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20. | Compliance with Authority Required procedures - Streamlined Authority Code 10077 |
| C10093 | P10093 | CN10093 | Fingolimod | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy; | Compliance with Authority Required procedures - Streamlined Authority Code 10093 |

Clause 1

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| | | | | Patient must weigh 40 kg or less. | |
| C10095 | P10095 | CN10095 | Prednisolone with phenylephrine | Severe eye inflammation<br>Patient must have had a cataract removed in the treated eye; or<br>Patient must be scheduled for cataract surgery in the treated eye;<br>Patient must identify as Aboriginal or Torres Strait Islander. | |
| C10116 | P10116 | CN10116 | Dolutegravir with abacavir and lamivudine | HIV infection<br>Continuing treatment<br>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<br>Initial treatment<br>The treatment must be adjuvant to complete surgical resection; AND<br>Patient must have a WHO performance status of 1 or less; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have received prior PBS-subsidised treatment for this condition; AND<br>The treatment must commence within 12 weeks of complete resection; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures |
| C10120 | P10120 | CN10120 | Nivolumab | Resected Stage IIIB, IIIC, IIID or Stage IV malignant melanoma<br>Continuing treatment<br>Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND<br>Patient must not have experienced disease recurrence; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |

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| | | | | 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. | |
| C10121 | P10121 | CN10121 | Budesonide with formoterol<br>Fluticasone furoate with vilanterol<br>Fluticasone propionate with salmeterol | Chronic obstructive pulmonary disease (COPD)<br>Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy; AND<br>Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 10121 |
| C10125 | P10125 | CN10125 | Atezolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment 2<br>Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy; AND<br>The condition must be non-squamous type non-small cell lung cancer (NSCLC); AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>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<br>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<br>Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 10125 |
| C10126 | P10126 | CN10126 | Durvalumab | Unresectable Stage III non-small cell lung cancer<br>Initial treatment<br>Patient must have received platinum based chemoradiation therapy; AND<br>The condition must not have progressed following platinum based chemoradiation therapy; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 10126 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. | |
| C10130 | P10130 | CN10130 | Dabrafenib<br>Trametinib | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma<br>Continuing treatment<br>Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection; AND<br>Patient must not have experienced disease recurrence; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| C10138 | P10138 | CN10138 | Levodopa with carbidopa | Advanced Parkinson disease<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>The treatment must be commenced in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10138 |
| C10139 | P10139 | CN10139 | Dimethyl fumarate | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug.<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10139 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10140 | P10140 | CN10140 | Dimethyl fumarate | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10140 |
| C10148 | P10148 | CN10148 | Dabrafenib<br>Trametinib | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma<br>Initial treatment<br>The treatment must be adjuvant to complete surgical resection; AND<br>The condition must be positive for a BRAF V600 mutation; AND<br>Patient must have a WHO performance status of 1 or less; AND<br>Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition; AND<br>Patient must not have received prior PBS-subsidised treatment for this condition; AND<br>The treatment must commence within 12 weeks of complete resection; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| C10150 | P10150 | CN10150 | Teriflunomide | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or | Compliance with Authority Required procedures - |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Streamlined Authority Code 10150 |
| C10157 | P10157 | CN10157 | Dabrafenib<br>Vemurafenib | Unresectable Stage III or Stage IV malignant melanoma<br>Initial treatment<br>The condition must be positive for a BRAF V600 mutation; AND<br>The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; or<br>Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal; AND<br>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<br>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<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>The treatment must be commenced in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10161 |
| C10162 | P10162 | CN10162 | Fingolimod<br>Ofatumumab | Multiple sclerosis<br>Initial treatment | Compliance with Authority Required procedures - |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | Ozanimod | The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Streamlined Authority Code 10162 |
| C10170 | P10170 | CN10170 | Cladribine | Relapsing remitting multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed by a neurologist; AND<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support).<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.<br>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 | Compliance with Authority Required procedures - Streamlined Authority Code 10170 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1. | |
| C10171 | P10171 | CN10171 | Cladribine | Relapsing remitting multiple sclerosis<br>Continuing treatment<br>Must be treated by a neurologist; AND<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.<br>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<br>Ofatumumab<br>Ozanimod | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10172 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10197 | P10197 | CN10197 | Levodopa with carbidopa | Advanced Parkinson disease<br>Maintenance therapy<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>Patient must have been commenced on treatment in a hospital-based movement disorder clinic. | Compliance with Authority Required procedures - Streamlined Authority Code 10197 |
| C10198 | P10198 | CN10198 | Fingolimod | Multiple sclerosis<br>Initial treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory (without assistance or support);<br>Patient must weigh 40 kg or less.<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10198 |
| C10199 | P10199 | CN10199 | Teriflunomide | Multiple sclerosis<br>Continuing treatment<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or<br>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND | Compliance with Authority Required procedures - Streamlined Authority Code 10199 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug.<br>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | |
| C10206 | P10206 | CN10206 | Atezolizumab<br>Durvalumab | Extensive-stage small cell lung cancer<br>Initial treatment<br>The condition must be previously untreated; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>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<br>Continuing treatment<br>Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND<br>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<br>Initial treatment<br>Must be treated by a neurologist; AND<br>The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents; AND<br>The treatment must 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<br>3 weekly treatment regimen | Compliance with Authority Required procedures - |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND<br>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND<br>Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. or<br>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.<br>Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Streamlined Authority Code 10212 |
| C10213 | P10213 | CN10213 | Trastuzumab | Early HER2 positive breast cancer<br>Continuing treatment (weekly regimen)<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND<br>Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. or<br>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<br>Continuing treatment - 4 weekly treatment regimen<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10215 |
| C10216 | P10216 | CN10216 | Atezolizumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen<br>Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated; AND | Compliance with Authority Required procedures - |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment; AND<br>Patient must have stable or responding disease. | Streamlined Authority Code 10216 |
| C10223 | P10223 | CN10223 | Omalizumab | Uncontrolled severe allergic asthma<br>Balance of supply in a patient aged 6 to 12 years<br>Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician; AND<br>Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; or<br>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction. | Compliance with Authority Required procedures |
| C10226 | P10226 | CN10226 | Omalizumab | Uncontrolled severe allergic asthma<br>Continuing treatment<br>Patient must have a documented history of severe allergic asthma; AND<br>Patient must have demonstrated or sustained an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.<br>An adequate response to omalizumab treatment is defined as<br>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR<br>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR<br>(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline. | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.<br>The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab.<br>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.<br>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Paediatric Severe Allergic Asthma Continuing PBS Authority Application - Supporting Information form which includes details of<br>(i) maintenance oral corticosteroid dose; and<br>(ii) Asthma Control Questionnaire (ACQ-5) score; or<br>(iii) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10248 | P10248 | CN10248 | Sofosbuvir with velpatasvir and voxilaprevir | Chronic hepatitis C infection<br>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND<br>Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND<br>The treatment must be limited to a maximum duration of 12 weeks.<br>The application must include details of the prior treatment regimen containing an NS5A inhibitor.<br>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)<br>Initial treatment<br>Must be treated by a nephrologist; AND<br>Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min 1.73 $m^2$ at the initiation of treatment with this drug for this condition; AND<br>Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition.<br>Rapidly progressing disease is defined as either of the following<br>A decline in eGFR of greater than or equal to 5 mL/min/1.73 $m^2$ within one year;<br>OR<br>An average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 $m^2$ per year over a five year period. | Compliance with Authority Required procedures |
| C10251 | P10251 | CN10251 | Brivaracetam | Intractable partial epileptic seizures<br>Initial treatment<br>Must be treated by a neurologist; AND<br>The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents; AND | Compliance with Authority Required procedures - Streamlined Authority Code 10251 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be unable to take a solid dose form of this drug; AND<br>The treatment must not be given concomitantly with levetiracetam, except for cross titration. | |
| C10252 | P10252 | CN10252 | Trifluridine with tipiracil | Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction<br>Initial treatment<br>Patient must have a WHO performance status of 1 or less; AND<br>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<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>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)<br>Continuing first-line treatment of metastatic disease, as monotherapy, where concomitant bevacizumab has ceased due to intolerance - 4 weekly treatment regimen<br>Patient must have experienced intolerance to combination treatment with bevacizumab; AND<br>Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment; AND<br>Patient must have stable or responding disease; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10257 |
| C10265 | P10265 | CN10265 | Omalizumab | Uncontrolled severe allergic asthma<br>Initial treatment<br>Patient must have a diagnosis of asthma confirmed and documented by a paediatric respiratory physician, clinical immunologist, or allergist; or paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by the following standard clinical features:<br>forced expiratory volume (FEV1) reversibility or airway hyperresponsiveness or peak expiratory flow (PEF) variability; AND<br>Patient must have a duration of asthma of at least 1 year; AND | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE; AND<br>Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL; AND<br>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 6 to less than 12 years;<br>Must be treated by a paediatric respiratory physician, clinical immunologist, allergist; or paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician; AND<br>Patient must be under the care of the same physician for at least 6 months.<br>Optimised asthma therapy includes<br>(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;<br>(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.<br>AND<br>(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.<br>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.<br>The initial IgE assessment must be no more than 12 months old at the time of application.<br>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),<br>(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.<br>(a) a completed authority prescription form; and<br>(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form,<br>(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the IgE result; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score; or<br>(v) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.<br>AND<br>(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.<br>(a) a completed authority prescription form; and<br>(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form,<br>(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the IgE result; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score; or | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (v) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.<br>The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with omalizumab.<br>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.<br>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Paediatric Severe Allergic Asthma Initial PBS Authority Application - Supporting Information form,<br>(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the IgE result; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score; or<br>(v) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | which includes the following<br>(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the IgE result; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score; or<br>(v) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score. | |
| C10268 | P10268 | CN10268 | Glecaprevir with pibrentasvir | Chronic hepatitis C infection<br>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND<br>Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND<br>The treatment must be limited to a maximum duration of 16 weeks.<br>The application must include details of the prior treatment regimen containing an NS5A inhibitor.<br>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<br>Initial treatment<br>The condition must be positive for a BRAF V600 mutation; AND<br>The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; or<br>Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal; AND<br>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<br>Patient must have a WHO performance status of 2 or less. | Compliance with Authority Required procedures - Streamlined Authority Code 10271 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10293 | P10293 | CN10293 | Trastuzumab | Early HER2 positive breast cancer<br>Initial treatment (3 weekly regimen)<br>Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND<br>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND<br>Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. or<br>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.<br>HER2 positivity must be demonstrated by in situ hybridisation (ISH).<br>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 10293 |
| C10294 | P10294 | CN10294 | Trastuzumab | Early HER2 positive breast cancer<br>Continuing treatment (3 weekly regimen)<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND<br>Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. or<br>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 |
| C10295 | P10295 | CN10295 | Trastuzumab emtansine | Early HER2 positive breast cancer<br>Continuing adjuvant treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. | |
| C10296 | P10296 | CN10296 | Trastuzumab | Early HER2 positive breast cancer<br>Initial treatment (weekly regimen)<br>Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND<br>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND<br>Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy. or<br>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.<br>HER2 positivity must be demonstrated by in situ hybridisation (ISH).<br>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 10296 |
| C10297 | P10297 | CN10297 | Atezolizumab | Locally advanced or metastatic non-small cell lung cancer<br>Continuing treatment - 3 weekly treatment regimen<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND<br>Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10297 |
| C10306 | P10306 | CN10306 | Binimetinib | Unresectable Stage III or Stage IV malignant melanoma<br>Continuing treatment<br>Patient must have previously been issued with an authority prescription for this drug; AND<br>Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition; AND<br>Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10306 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10309 | P10309 | CN10309 | Trifluridine with tipiracil | Metastatic colorectal cancer<br>Initial treatment<br>Patient must have a WHO performance status of 1 or less; AND<br>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<br>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<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>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<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition; AND<br>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<br>Continuing treatment<br>Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner; AND<br>Patient must have previously received PBS-subsidised therapy for HIV infection; AND<br>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<br>Initial treatment<br>Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner; AND | Compliance with Authority Required procedures - |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be antiretroviral treatment naive; or<br>Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen; AND<br>The treatment must not be in combination with ritonavir.<br>Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. | Streamlined Authority Code 10324 |
| C10328 | P10328 | CN10328 | Binimetinib | Unresectable Stage III or Stage IV malignant melanoma<br>Initial treatment<br>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<br>Continuing treatment<br>Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND<br>Patient must be unable to take a solid dose form of this drug; AND<br>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<br>Continuing treatment<br>Must be treated by a metabolic physician; or<br>Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND<br>Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition.<br>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 | Compliance with Authority Required |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be in the third trimester of pregnancy; AND<br>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. | procedures - Streamlined Authority Code 10362 |
| C10363 | P10363 | CN10363 | Levodopa with carbidopa | Advanced Parkinson disease<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>The treatment must be commenced in a hospital-based movement disorder clinic; AND<br>Patient must require continuous administration of levodopa without an overnight break. or<br>Patient must require a total daily dose of more than 2000 mg of levodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 10363 |
| C10375 | P10375 | CN10375 | Levodopa with carbidopa | Advanced Parkinson disease<br>Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>The treatment must be commenced in a hospital-based movement disorder clinic; AND<br>Patient must require continuous administration of levodopa without an overnight break. or<br>Patient must require a total daily dose of more than 2000 mg of levodopa. | Compliance with Authority Required procedures - Streamlined Authority Code 10375 |
| C10384 | P10384 | CN10384 | Brigatinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment<br>The treatment must be as monotherapy; AND<br>The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND<br>Patient must have a WHO performance status of 2 or less;<br>Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing. | Compliance with Authority Required procedures |
| C10386 | P10386 | CN10386 | Levodopa with carbidopa | Advanced Parkinson disease<br>Maintenance therapy | Compliance with Authority Required procedures - |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND<br>Patient must have been commenced on treatment in a hospital-based movement disorder clinic; AND<br>Patient must require continuous administration of levodopa without an overnight break. or<br>Patient must require a total daily dose of more than 2000 mg of levodopa. | Streamlined Authority Code 10386 |
| C10388 | P10388 | CN10388 | Evolocumab | Familial homozygous hypercholesterolaemia<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>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<br>Continuing treatment<br>Must be treated by a metabolic physician; or<br>Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND<br>Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition.<br>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<br>Initial treatment<br>Must be treated by a metabolic physician; AND<br>Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.<br>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 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10402 | P10402 | CN10402 | Amoxicillin | Infection<br>Patient must be a male with acute cystitis. or<br>Patient must have pyelonephritis. or<br>Patient must have a tooth avulsion. or<br>Patient must have salmonella enteritis. or<br>Patient must have community acquired pneumonia. or<br>Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10402 |
| C10404 | P10404 | CN10404 | Amoxicillin<br>Roxithromycin | Infection<br>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<br>Patient must be a male with acute cystitis. or<br>Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10405 |
| C10410 | P10410 | CN10410 | Cefalexin | Infection<br>Patient must have a pin-site infection. or<br>Patient must have an infection following cardiac device insertion. or<br>Patient must have acute otitis externa. or<br>Patient must have streptococcal pharyngitis or tonsillitis. or<br>Patient must have mastitis. or<br>Patient must have periorbital (preseptal) cellulitis. or<br>Patient must have acute rheumatic fever. or<br>Patient must have a diabetic foot infection. or<br>Patient must have a widespread infection of dermatitis.<br>Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection. or<br>Patient must have impetigo. or | Compliance with Authority Required procedures - Streamlined Authority Code 10410 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have pyelonephritis. or<br>Patient must have a condition requiring prolonged oral antibiotic therapy. or<br>Midwives may prescribe under this item for the treatment of mastitis only. | |
| C10412 | P10412 | CN10412 | Cefalexin | Infection<br>Patient must have impaired renal function; AND<br>Patient must have a pin-site infection. or<br>Patient must have an infection following cardiac device insertion. or<br>Patient must have acute otitis externa. or<br>Patient must have streptococcal pharyngitis or tonsillitis. or<br>Patient must have mastitis. or<br>Patient must have periorbital (preseptal) cellulitis. or<br>Patient must have acute rheumatic fever. or<br>Patient must have a diabetic foot infection. or<br>Patient must have a widespread infection of dermatitis.<br>Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection. or<br>Patient must have impetigo. or<br>Patient must have pyelonephritis. or<br>Patient must have a condition requiring prolonged oral antibiotic therapy. or<br>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<br>Patient must have periorbital (preseptal) cellulitis. or<br>Patient must have postpartum endometritis. or<br>Patient must have an exacerbation of bronchiectasis. or<br>Patient must have pyelonephritis. or<br>Patient must have pneumonia acquired in hospital or aged care. or<br>Patient must have a diabetic foot infection. or<br>Patient must have a condition requiring prolonged oral antibiotic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10413 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10414 | P10414 | CN10414 | Pertuzumab | Metastatic (Stage IV) HER2 positive breast cancer<br>Continuing treatment<br>Patient must have previously been issued with an authority prescription for this drug for this condition; AND<br>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND<br>The treatment must be in combination with trastuzumab; AND<br>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>The treatment must not exceed a lifetime total of one course. However, treatment breaks are permitted. A patient who has a treatment break in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug.<br>Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment. | Compliance with Authority Required procedures |
| C10416 | P10416 | CN10416 | Amoxicillin | Community acquired pneumonia<br>Patient must have community acquired pneumonia. | Compliance with Authority Required procedures - Streamlined Authority Code 10416 |
| C10431 | P10431 | CN10431 | Certolizumab pegol<br>Secukinumab | Non-radiographic axial spondyloarthritis<br>Continuing treatment<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND<br>The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction; AND<br>Must be treated by a rheumatologist. or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.<br>An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following<br>(a) a CRP measurement no greater than 10 mg per L; or<br>(b) a CRP measurement reduced by at least 20% from baseline.<br>If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.<br>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. | |
| C10434 | P10434 | CN10434 | Golimumab<br>Upadacitinib | Non-radiographic axial spondyloarthritis<br>Continuing treatment - balance of supply<br>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment; AND<br>Must be treated by a rheumatologist. or<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C10436 | P10436 | CN10436 | Golimumab | Non-radiographic axial spondyloarthritis<br>Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 16 weeks treatment; AND<br>Must be treated by a rheumatologist. or<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | |
| C10459 | P10459 | CN10459 | Certolizumab pegol | Non-radiographic axial spondyloarthritis<br>Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 20 weeks treatment; AND<br>Must be treated by a rheumatologist. or<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C10464 | P10464 | CN10464 | Budesonide with formoterol | Mild asthma<br>Patient must have asthma and require an anti-inflammatory reliever therapy; AND | Compliance with Authority Required procedures - |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).<br>Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine. | Streamlined Authority Code 10464 |
| C10482 | P10482 | CN10482 | Budesonide with formoterol | Mild asthma<br>Patient must have asthma and require an anti-inflammatory reliever therapy; AND<br>Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA);<br>Patient must be aged 12 years or over.<br>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<br>The condition must be associated with radiotherapy being used to treat malignancy. or<br>The condition must be associated with oral chemotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 10498 |
| C10509 | P10509 | CN10509 | Atezolizumab<br>Durvalumab | Extensive-stage small cell lung cancer<br>Continuing treatment - 4 weekly treatment regimen<br>The treatment must be as monotherapy; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while 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<br>Continuing treatment - 3 weekly treatment regimen<br>The treatment must be as monotherapy; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 10521 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10538 | P10538 | CN10538 | Budesonide with formoterol | Asthma<br>Patient must have failed PBS-subsidised fluticasone proprionate and salmeterol as a fixed dose combination for this condition; AND<br>Must be treated by a respiratory physician. or<br>Must be treated by a paediatrician. | Compliance with Authority Required procedures - Streamlined Authority Code 10538 |
| C10560 | P10560 | CN10560 | Tocilizumab | Systemic juvenile idiopathic arthritis<br>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<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; or<br>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<br>The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; AND<br>Must be treated by a rheumatologist. or<br>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. | Compliance with Authority Required procedures |
| C10570 | P10570 | CN10570 | Tocilizumab | Systemic juvenile idiopathic arthritis<br>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)<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; AND<br>Must be treated by a rheumatologist. or<br>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. | |
| C10676 | P10676 | CN10676 | Pembrolizumab | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma<br>Continuing treatment - 6 weekly treatment regimen<br>Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND<br>Patient must not have experienced disease recurrence; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| C10688 | P10688 | CN10688 | Pembrolizumab | Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma<br>Initial treatment - 6 weekly treatment regimen<br>The treatment must be adjuvant to complete surgical resection; AND<br>Patient must have a WHO performance status of 1 or less; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not have received prior PBS-subsidised treatment for this condition; AND<br>The treatment must commence within 12 weeks of complete resection; AND<br>Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. | Compliance with Authority Required procedures |
| C10701 | P10701 | CN10701 | Pembrolizumab | Unresectable Stage III or Stage IV malignant melanoma<br>Continuing treatment - 6 weekly treatment regimen<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously been issued with an authority prescription for this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 10701 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have stable or responding disease. | |
| C10705 | P10705 | CN10705 | Pembrolizumab | Unresectable Stage III or Stage IV malignant melanoma<br>Continuing treatment - 3 weekly treatment regimen<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously been issued with an authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 10705 |
| C10717 | P10717 | CN10717 | Methylphenidate | Attention deficit hyperactivity disorder<br>Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive;<br>Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND<br>Patient must require continuous coverage over 12 hours; AND<br>The treatment must not exceed a maximum daily dose of 72 mg with this drug. | Compliance with Authority Required procedures |
| C10742 | P10742 | CN10742 | Guselkumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10743 | P10743 | CN10743 | Guselkumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |
| C10745 | P10745 | CN10745 | Fentanyl<br>Methadone | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must not be opioid naive; AND<br>Patient must have cancer pain. or<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. | Compliance with Authority Required procedures - Streamlined Authority Code 10745 |
| C10747 | P10747 | CN10747 | Fentanyl<br>Methadone | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must not be opioid naive; AND<br>Patient must have cancer pain. or<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>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 10747 |
| C10748 | P10748 | CN10748 | Buprenorphine<br>Morphine<br>Oxycodone<br>Oxycodone with naloxone | Chronic severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain. or | Compliance with Authority Required procedures - Streamlined Authority Code 10748 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | Tapentadol<br>Tramadol | Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10751 | P10751 | CN10751 | Fentanyl<br>Methadone | Chronic severe disabling pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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 10751 |
| C10752 | P10752 | CN10752 | Buprenorphine<br>Morphine<br>Oxycodone<br>Oxycodone with naloxone<br>Tapentadol<br>Tramadol | Chronic severe pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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<br>Morphine<br>Oxycodone<br>Oxycodone with naloxone<br>Tapentadol<br>Tramadol | Chronic severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain. or<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. | Compliance with Authority Required procedures - Streamlined Authority Code 10755 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10756 | P10756 | CN10756 | Morphine | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain. or<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or<br>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<br>The treatment must be for short term therapy of acute severe pain; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. | |
| C10762 | P10762 | CN10762 | Morphine | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. or<br>The treatment must be part of pre-operative care. or<br>The treatment must be used as an analgesic adjunct in general anaesthesia.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10764 | P10764 | CN10764 | Codeine<br>Codeine with paracetamol<br>Hydromorphone<br>Morphine | Severe pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | Oxycodone<br>Tramadol | Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10765 | P10765 | CN10765 | Morphine | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. or<br>The treatment must be part of pre-operative care. or<br>The treatment must be used as an analgesic adjunct in general anaesthesia. | |
| C10766 | P10766 | CN10766 | Codeine<br>Codeine with paracetamol<br>Oxycodone<br>Tramadol | Severe pain<br>The treatment must be for short term therapy of acute severe pain; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. | |
| C10768 | P10768 | CN10768 | Codeine<br>Codeine with paracetamol<br>Oxycodone<br>Tramadol | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. | |
| C10770 | P10770 | CN10770 | Hydromorphone<br>Morphine | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. | |

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| | | | | Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10771 | P10771 | CN10771 | Codeine<br>Codeine with paracetamol<br>Oxycodone<br>Tramadol | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. | |
| C10772 | P10772 | CN10772 | Codeine<br>Codeine with paracetamol<br>Oxycodone<br>Tramadol | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10775 | P10775 | CN10775 | Morphine | Cancer pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have cancer pain; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10777 | P10777 | CN10777 | Hydromorphone<br>Morphine | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months | |

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| | | | | Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. | |
| C10792 | P10792 | CN10792 | Lisdexamfetamine | Attention deficit hyperactivity disorder<br>Patient must require continuous coverage over 12 hours; AND<br>The treatment must not exceed a maximum daily dose of 70 mg with this drug;<br>Patient must be aged between the ages of 6 and 18 years inclusive. or<br>Patient must have had a diagnosis of ADHD prior to turning 18 years of age if PBS-subsidised treatment is continuing beyond 18 years of age. or<br>Patient must have a retrospective diagnosis of ADHD if PBS-subsidised treatment is commencing after turning 18 years of age. or<br>Patient must have had a retrospective diagnosis of ADHD if PBS-subsidised treatment is continuing in a patient who commenced PBS-subsidised treatment after turning 18 years of age.<br>A retrospective diagnosis of ADHD for the purposes of administering this restriction is<br>(i) the presence of pre-existing childhood symptoms of ADHD (onset during the developmental period, typically early to mid-childhood); and<br>(ii) documentation in the patient's medical records that an in-depth clinical interview with, or, obtainment of evidence from, either a (a) parent, (b) teacher, (c) sibling, (d) third party, has occurred and which supports point (i) above. | Compliance with Authority Required procedures |
| C10802 | P10802 | CN10802 | Risankizumab<br>Tildrakizumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |
| C10806 | P10806 | CN10806 | Guselkumab<br>Tildrakizumab | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C10807 | P10807 | CN10807 | Bimekizumab<br>Guselkumab<br>Tildrakizumab | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply<br>Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; or<br>Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND<br>Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C10814 | P10814 | CN10814 | Morphine | Chronic severe disabling pain<br>Continuing PBS treatment after 1 June 2020<br>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>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<br>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND<br>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<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain. or<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. | Compliance with Authority Required procedures |
| C10837 | P10837 | CN10837 | Morphine | Cancer pain<br>Continuing PBS treatment after 1 June 2020 | |

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| | | | | Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10839 | P10839 | CN10839 | Morphine | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. or<br>The treatment must be part of pre-operative care. or<br>The treatment must be used as an analgesic adjunct in general anaesthesia. | |
| C10844 | P10844 | CN10844 | Apomorphine | Parkinson disease<br>Maintenance therapy<br>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND<br>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 | Risankizumab<br>Tildrakizumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:<br>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction; | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |
| C10858 | P10858 | CN10858 | Morphine | Chronic severe disabling pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>The condition must require daily, continuous, long term opioid treatment; AND<br>Patient must have cancer pain. or<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics. or | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10859 | P10859 | CN10859 | Hydromorphone<br>Morphine | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. | |
| C10860 | P10860 | CN10860 | Oxycodone | Severe pain<br>The treatment must be for post-operative pain following a major operative procedure; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. | |
| C10863 | P10863 | CN10863 | Apomorphine | Parkinson disease<br>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND<br>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<br>Tildrakizumab | Severe chronic plaque psoriasis<br>Continuing treatment, Face, hand, foot<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist. | Compliance with Written Authority Required procedures |

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| | | | | An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was | |

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| | | | | approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C10890 | P10890 | CN10890 | Oxycodone | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months<br>Patient must have cancer pain; or<br>The treatment must be for post-operative pain following a major operative procedure; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.<br>Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. | |
| C10891 | P10891 | CN10891 | Morphine | Cancer pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months<br>Patient must have cancer pain; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics. or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. | |
| C10901 | P10901 | CN10901 | Guselkumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:<br>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom | Compliance with Written Authority Required procedures |

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| | | | | subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |
| C10910 | P10910 | CN10910 | Oxycodone | Severe pain<br>Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months | |

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| | | | | Patient must have cancer pain; or<br>The treatment must be for post-operative pain following a major operative procedure; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics. or<br>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. | |
| C10917 | P10917 | CN10917 | Atezolizumab | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma<br>Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen<br>Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition.<br>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<br>Modafinil | Narcolepsy<br>Initial 2 - treatment of narcolepsy with cataplexy<br>Must be treated by a qualified sleep medicine practitioner or neurologist; AND<br>The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; or<br>The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal; AND<br>Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months; AND<br>Patient must have a definite history of cataplexy documented in their medical records for auditing purposes; AND<br>Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia. | Compliance with Authority Required procedures |

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| | | | | The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk<br>(a) a psychiatric disorder;<br>(b) a cardiovascular disorder;<br>(c) a history of substance abuse;<br>(d) glaucoma;<br>(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information. | |
| C10939 | P10939 | CN10939 | Atezolizumab | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma<br>Initial treatment<br>Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>Patient must not be suitable for transarterial chemoembolisation; AND<br>Patient must have Child Pugh class A; AND<br>The condition must be untreated with systemic therapy. or<br>Patient must have developed intolerance 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<br>Continuing treatment (including recommencement of treatment)<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not show continuing progression of disability while on treatment with this drug; AND<br>Patient must be ambulatory, with/without assistance/support; AND<br>Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10953 |

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| C10955 | P10955 | CN10955 | Siponimod | Multiple sclerosis<br>Initial treatment<br>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<br>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<br>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND<br>Patient must be ambulatory, with/without assistance/support; AND<br>Patient must have mild disability in at least 3 functional systems. or<br>Patient must have moderate disability in at least 1 functional system.<br>Functional systems referred to in this restriction are the visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems.<br>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<br>Continuing or change of treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. or<br>Patient must have previously received PBS-subsidised treatment with modafinil for this condition. | Compliance with Authority Required procedures |
| C10968 | P10968 | CN10968 | Modafinil | Narcolepsy<br>Continuing or change of treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. or<br>Patient must have previously received PBS-subsidised treatment with armodafinil for this condition. | Compliance with Authority Required procedures |

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| C10970 | P10970 | CN10970 | Armodafinil<br>Modafinil | Narcolepsy<br>Initial 1 - treatment of narcolepsy without cataplexy<br>Must be treated by a qualified sleep medicine practitioner or neurologist; AND<br>The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; or<br>The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal; AND<br>Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months; AND<br>Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); or<br>Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; AND<br>Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.<br>The presence of any one of the following indicates treatment with dexamfetamine sulfate poses an unacceptable medical risk<br>(a) a psychiatric disorder;<br>(b) a cardiovascular disorder;<br>(c) a history of substance abuse;<br>(d) glaucoma;<br>(e) any other absolute contraindication to dexamfetamine sulfate as specified in the TGA-approved Product Information.<br>The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.<br>The authority application must be made in writing and must include the following<br>(a) a completed authority prescription form; and<br>(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and<br>(c) details of the contraindication or intolerance to dexamfetamine sulfate; and<br>(d) either | Compliance with Written Authority Required procedures |

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| | | | | (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or<br>(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.<br>The polysomnography, MSLT or EEG test reports must be provided with the authority application. | |
| C10971 | P10971 | CN10971 | Methoxsalen | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma<br>Initial treatment<br>Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; or<br>Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; or<br>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND<br>Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication; AND<br>Must be treated by a haematologist; or<br>Must be treated by a medical physician working under the supervision of a haematologist;<br>Patient must be aged 18 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 10971 |
| C10972 | P10972 | CN10972 | Atezolizumab | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma<br>Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 10972 |

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| | | | | Patient must not have developed disease progression while being treated with this drug for this condition.<br>PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time | |
| C10985 | P10985 | CN10985 | Methoxsalen | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma<br>Initial treatment<br>Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; or<br>Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; or<br>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND<br>Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication; AND<br>Must be treated by a haematologist; or<br>Must be treated by a medical physician working under the supervision of a haematologist;<br>Patient must be aged 18 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 10985 |
| C10988 | P10988 | CN10988 | Methoxsalen | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma<br>Continuing treatment<br>Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND<br>Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; or | Compliance with Authority Required procedures - Streamlined Authority Code 10988 |

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| | | | | The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND<br>Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule; AND<br>Must be treated by a haematologist. or<br>Must be treated by a medical physician working under the supervision of a haematologist.<br>A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment | |
| C10989 | P10989 | CN10989 | Methoxsalen | Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma<br>Continuing treatment<br>Patient must have received PBS-subsidised treatment with this drug for this PBS indication; AND<br>Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; or<br>The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug; AND<br>Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule; AND<br>Must be treated by a haematologist. or<br>Must be treated by a medical physician working under the supervision of a haematologist.<br>A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for | Compliance with Authority Required procedures - Streamlined Authority Code 10989 |

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| | | | | PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment | |
| C10992 | P10992 | CN10992 | Rivaroxaban | Chronic stable atherosclerotic disease<br>Continuing treatment<br>Patient must have received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with aspirin, but not with any other anti-platelet therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 10992 |
| C10995 | P10995 | CN10995 | Venetoclax | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Dose modification<br>The treatment must be for dose titration purposes. | Compliance with Authority Required procedures |
| C11013 | P11013 | CN11013 | Rivaroxaban | Chronic stable atherosclerotic disease<br>Initial treatment<br>The treatment must be in combination with aspirin, but not with any other anti-platelet therapy; AND<br>Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors:<br>(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<br>Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors:<br>(i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; AND<br>Patient must have at least one of the following if coronary artery disease is present:<br>(i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary | Compliance with Authority Required procedures - Streamlined Authority Code 11013 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | revascularisation procedure with significant stenosis in more than 1 coronary artery; or<br>Patient must have at least one of the following if peripheral arterial disease is present:<br>(i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%; AND<br>The condition must be diagnosed by at least one of:<br>(i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication; AND<br>Patient must have clinical findings/observations by the treating physician that exclude each of the following:<br>(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<br>Must be treated by a specialist physician. or<br>Must be treated by a physician who has consulted a specialist physician. | |
| C11015 | P11015 | CN11015 | Obinutuzumab | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>For combination use with venetoclax treatment cycles 1 to 6 inclusive in first-line therapy<br>The condition must be untreated; AND<br>The treatment must be in combination with PBS-subsidised venetoclax. | Compliance with Authority Required procedures - Streamlined Authority Code 11015 |
| C11017 | P11017 | CN11017 | Venetoclax | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>First continuing treatment (treatment cycles 2 to 6 inclusive) of first-line therapy<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures |

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| | | | | The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses); AND<br>The treatment must cease upon disease progression. | |
| C11018 | P11018 | CN11018 | Rifampicin | Mycobacterium ulcerans infection (Buruli ulcer)<br>The treatment must be used in combination with another antibiotic for the treatment of Buruli ulcer. | Compliance with Authority Required procedures |
| C11057 | P11057 | CN11057 | Beclometasone with formoterol | Asthma<br>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids;<br>Patient must be aged 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 11057 |
| C11066 | P11066 | CN11066 | Dolutegravir with lamivudine | HIV infection<br>Continuing or change of treatment<br>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)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy; AND<br>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<br>Patient must be a child aged 3 years or older;<br>Patient must require treatment with a low protein and a low phosphorus diet. or<br>Patient must require treatment with a low protein, low phosphorus and low potassium diet. | Compliance with Authority Required procedures - Streamlined Authority Code 11070 |

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| C11073 | P11073 | CN11073 | Venetoclax | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Second and final continuing treatment prescription (treatment cycles 7 to 12 inclusive) of first-line therapy<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must cease upon disease progression. or<br>The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first. | Compliance with Authority Required procedures |
| C11077 | P11077 | CN11077 | Levetiracetam | Partial epileptic seizures<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or<br>Patient must be a woman of childbearing potential; AND<br>Patient must be unable to take a solid dose form of levetiracetam; AND<br>The treatment must not be given concomitantly with brivaracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 11077 |
| C11081 | P11081 | CN11081 | Lamotrigine | Epileptic seizures<br>The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. or<br>Patient must be a woman of childbearing potential. | Compliance with Authority Required procedures - Streamlined Authority Code 11081 |
| C11089 | P11089 | CN11089 | Ixekizumab<br>Secukinumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:<br>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; | Compliance with Written Authority Required procedures |

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| | | | | or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |
| C11090 | P11090 | CN11090 | Tildrakizumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years) | Compliance with Written Authority Required procedures |

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| | | | | Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following | |

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| | | | | (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | |
| C11096 | P11096 | CN11096 | Ixekizumab<br>Secukinumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11099 | P11099 | CN11099 | Bortezomib | Multiple myeloma | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11107 | P11107 | CN11107 | Adalimumab<br>Etanercept<br>Ixekizumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND<br>Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C11116 | P11116 | CN11116 | Levetiracetam | Partial epileptic seizures | Compliance with Authority Required |

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| | | | | The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; or<br>Patient must be a woman of childbearing potential; AND<br>The treatment must not be given concomitantly with brivaracetam, except for cross titration. | procedures - Streamlined Authority Code 11116 |
| C11119 | P11119 | CN11119 | Ustekinumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11120 | P11120 | CN11120 | Risankizumab<br>Tildrakizumab<br>Ustekinumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction; AND<br>Must be treated by a dermatologist. | |
| C11123 | P11123 | CN11123 | Tildrakizumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter. | |
| C11124 | P11124 | CN11124 | Risankizumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist. | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter. | |
| C11130 | P11130 | CN11130 | Guselkumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11138 | P11138 | CN11138 | Ixekizumab<br>Secukinumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11143 | P11143 | CN11143 | Tenofovir with emtricitabine | Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection<br>Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued:<br>(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<br>Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:<br>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older; | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>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.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |
| C11153 | P11153 | CN11153 | Ustekinumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11154 | P11154 | CN11154 | Ixekizumab<br>Secukinumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |
| C11158 | P11158 | CN11158 | Infliximab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 22 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; or | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions; AND<br>Must be treated by a dermatologist. | |
| C11160 | P11160 | CN11160 | Sorafenib | Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>Patient must have Child Pugh class A; AND<br>The condition must be untreated with systemic therapy. or<br>Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following:<br>(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<br>Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>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.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11168 | P11168 | CN11168 | Lenvatinib | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must not be suitable for transarterial chemoembolisation; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>Patient must have Child Pugh class A; AND<br>The condition must be untreated with systemic therapy. or<br>Patient must have developed intolerance of a severity necessitating permanent treatment withdrawal, in the absence of disease progression, to any of the following:<br>(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 |
| C11171 | P11171 | CN11171 | Risankizumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 28 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |

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| | | | | At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter. | |
| C11178 | P11178 | CN11178 | Osimertinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy<br>Patient must not have previously received this drug for this condition; AND<br>The treatment must be as monotherapy; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition; AND<br>Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment. | Compliance with Authority Required procedures |
| C11181 | P11181 | CN11181 | Osimertinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy<br>The treatment must be as monotherapy; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed). | Compliance with Authority Required procedures |
| C11183 | P11183 | CN11183 | Osimertinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures |

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| | | | | Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed). | |
| C11185 | P11185 | CN11185 | Osimertinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); or<br>Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal;<br>Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors. | Compliance with Authority Required procedures |
| C11193 | P11193 | CN11193 | Selexipag | Pulmonary arterial hypertension (PAH)<br>Continuing treatment<br>Patient must have received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); or<br>The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an | Compliance with Authority Required procedures |

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| | | | | endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'); AND<br>The treatment must not be as monotherapy; AND<br>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.<br>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.<br>For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred<br>(i) Hospitalisation due to worsening PAH;<br>(ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;<br>(iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;<br>(iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;<br>(v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH. | |
| C11195 | P11195 | CN11195 | Selexipag | Pulmonary arterial hypertension (PAH)<br>Initial treatment following dose titration<br>Patient must have WHO Functional Class III PAH at treatment initiation with this drug; or<br>Patient must have WHO Functional Class IV PAH at treatment initiation with this drug; AND<br>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); or<br>The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one | Compliance with Authority Required procedures |

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| | | | | phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'); AND<br>Patient must have completed the dose titration phase; AND<br>The treatment must not be as monotherapy; AND<br>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH;<br>Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.<br>Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.<br>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.<br>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.<br>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows<br>(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or<br>(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. | |
| C11229 | P11229 | CN11229 | Ambrisentan<br>Bosentan | Pulmonary arterial hypertension (PAH)<br>Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag | Compliance with Authority Required procedures |

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| | | | Macitentan<br>Sildenafil | The treatment must form part of triple combination therapy consisting of:<br>(i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); or | |
| | | | Tadalafil | The treatment must form part of dual combination therapy consisting of either:<br>(i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'); AND<br>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.<br>The authority application for selexipag must be approved prior to the authority application for this agent.<br>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.<br>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows<br>(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or<br>(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.<br>The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.<br>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.<br>A maximum of 5 repeats may be requested. | |

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| C11261 | P11261 | CN11261 | Selexipag | Pulmonary arterial hypertension (PAH)<br>Initial treatment - dose titration<br>Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy; AND<br>Patient must have WHO Functional Class III PAH at treatment initiation with this drug; or<br>Patient must have WHO Functional Class IV PAH at treatment initiation with this drug; AND<br>The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks; AND<br>The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); or<br>The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'); AND<br>The treatment must not be as monotherapy; AND<br>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH;<br>Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.<br>A prior PAH agent is any of ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.<br>For the purposes of PBS subsidy, an endothelin receptor antagonist is one of (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.<br>PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.<br>PAH (WHO Group 1 pulmonary hypertension) is defined as follows | Compliance with Authority Required procedures |

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| | | | | (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or<br>(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. | |
| C11310 | P11310 | CN11310 | Esomeprazole<br>Lansoprazole<br>Omeprazole<br>Pantoprazole<br>Rabeprazole | Complex gastro-oesophageal reflux disease (GORD)<br>One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control<br>Must be treated by a gastroenterologist; or<br>Must be treated by a surgeon with expertise in the upper gastrointestinal tract; or<br>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; or<br>Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes; AND<br>The treatment must be:<br>(i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND<br>Patient must must have symptoms inadequately controlled with each of:<br>(i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control. or<br>Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for:<br>(2) maintenance treatment. or<br>Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for:<br>(3) re-establishment of symptom control. or | Compliance with Authority Required procedures |

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| | | | | Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for:<br>(2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.<br>Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction. | |
| C11360 | P11360 | CN11360 | Indacaterol with mometasone | Asthma<br>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids;<br>Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 11360 |
| C11370 | P11370 | CN11370 | Esomeprazole | Complex gastro-oesophageal reflux disease (GORD)<br>One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control<br>Must be treated by a gastroenterologist; or<br>Must be treated by a surgeon with expertise in the upper gastrointestinal tract; AND<br>The treatment must be:<br>(i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI; AND<br>Patient must have symptoms inadequately controlled with each of:<br>(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<br>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:<br>(2) maintenance treatment. or<br>Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for:<br>(3) re-establishment of symptom control. or<br>Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: | Compliance with Authority Required procedures |

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| | | | | (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.<br>Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction. | |
| C11374 | P11374 | CN11374 | Dupilumab | Chronic severe atopic dermatitis<br>Continuing or resuming treatment of the whole body<br>Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body; AND<br>Patient must have achieved an adequate response within the first 16 weeks of treatment; or<br>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<br>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<br>The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND<br>Must be treated by a dermatologist. or<br>Must be treated by a clinical immunologist.<br>For the purposes of this restriction, an adequate response to treatment is defined as<br>(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and<br>(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline<br>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 | Compliance with Authority Required procedures |

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| | | | | the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.<br>State each of the current EASI and DLQI scores for this authority application. | |
| C11377 | P11377 | CN11377 | Dupilumab | Chronic severe atopic dermatitis<br>Continuing or resuming treatment of the face and/or hands<br>Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands; AND<br>Patient must have achieved an adequate response within the first 16 weeks of treatment; or<br>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<br>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<br>The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND<br>Must be treated by a dermatologist. or<br>Must be treated by a clinical immunologist.<br>For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as<br>(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<br>(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and<br>(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline<br>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 | Compliance with Authority Required procedures |

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| | | | | the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.<br>Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes | |
| C11385 | P11385 | CN11385 | Apomorphine | Parkinson disease<br>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND<br>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<br>Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patients) restriction to complete 20 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 20 weeks treatment; AND<br>Must be treated by a rheumatologist. or<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C11391 | P11391 | CN11391 | Ipilimumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Continuing combination treatment (with nivolumab) of first-line drug therapy<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 11391 |

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| | | | | Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND<br>The treatment must be in combination with nivolumab. | |
| C11445 | P11445 | CN11445 | Apomorphine | Parkinson disease<br>Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy; AND<br>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)<br>Continuing combination treatment (with ipilimumab) of first-line drug therapy<br>The condition must be squamous type non-small cell lung cancer (NSCLC); AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first; AND<br>The treatment must be in combination with ipilimumab. | Compliance with Authority Required procedures - Streamlined Authority Code 11468 |
| C11473 | P11473 | CN11473 | Fulvestrant | Locally advanced or metastatic breast cancer<br>The condition must be hormone receptor positive; AND<br>The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND<br>The condition must be inoperable;<br>Patient must not be premenopausal.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 11473 |
| C11477 | P11477 | CN11477 | Nivolumab | Locally advanced or metastatic non-small cell lung cancer<br>Continuing treatment as second-line drug therapy | Compliance with Authority Required procedures - |

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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND<br>Patient must have stable or responding disease.<br>Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Streamlined Authority Code 11477 |
| C11478 | P11478 | CN11478 | Ipilimumab | Stage IV (metastatic) non-small cell lung cancer (NSCLC)<br>Initial combination treatment (with nivolumab) as first-line drug therapy<br>The condition must be squamous type non-small cell lung cancer (NSCLC); AND<br>Patient must not have previously been treated for this condition in the metastatic setting; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND<br>The treatment must be in combination with platinum-based chemotherapy for the first two cycles; AND<br>The treatment must be in combination with nivolumab.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | 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<br>Patient must be managed on a low lysine diet for pyridoxine dependent epilepsy; AND<br>The condition must be treated by or in consultation with a metabolic physician. | |
| C11523 | P11523 | CN11523 | Adalimumab | Severe psoriatic arthritis<br>Subsequent continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND | Compliance with Authority Required procedures - Streamlined Authority Code 11523 |

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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The 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.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11524 | P11524 | CN11524 | Adalimumab | Complex refractory Fistulising Crohn disease<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>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<br>Patient must have demonstrated an adequate response to treatment with this drug for this condition.<br>An adequate response is defined as<br>(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or<br>(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>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<br>Subsequent continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated a response to treatment with this drug for this condition; AND<br>Must be treated by a dermatologist.<br>A response to treatment is defined as | Compliance with Authority Required procedures - Streamlined Authority Code 11529 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. | |
| C11579 | P11579 | CN11579 | Adalimumab | Moderate to severe ulcerative colitis<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or<br>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<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be 6 years of age or older.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>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 | Compliance with Authority Required procedures - Streamlined Authority Code 11579 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (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.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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. | |
| C11604 | P11604 | CN11604 | Adalimumab | Severe active juvenile idiopathic arthritis<br>Subsequent continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or<br>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or | Compliance with Authority Required procedures - Streamlined Authority Code 11604 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (c) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder, 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).<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. | |
| C11606 | P11606 | CN11606 | Adalimumab | Severe chronic plaque psoriasis<br>Subsequent continuing treatment, Face, hand, foot<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND | Compliance with Authority Required procedures - Streamlined Authority Code 11606 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11631 | P11631 | CN11631 | Adalimumab | Severe Crohn disease<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND | Compliance with Authority Required procedures - Streamlined Authority Code 11631 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11635 | P11635 | CN11635 | Adalimumab | Severe chronic plaque psoriasis<br>Subsequent continuing treatment, Whole body<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND | Compliance with Authority Required procedures - Streamlined Authority Code 11635 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11642 | P11642 | CN11642 | Stiripentol | Severe myoclonic epilepsy in infancy (Dravet syndrome)<br>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<br>The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs; AND<br>Must be treated by a neurologist if treatment is being initiated. or<br>Must be treated by a neurologist if treatment is being continued or re-initiated. or<br>Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued. or<br>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 | Ketogenic diet<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; or | |

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| | | | elements and low in protein and carbohydrate | Patient must have a glucose transport protein defect; or<br>Patient must have pyruvate dehydrogenase deficiency; AND<br>Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of:<br>(i) a metabolic physician, (ii) a neurologist. | |
| C11673 | P11673 | CN11673 | Progesterone | Prevention of preterm birth<br>Patient must have a singleton pregnancy; AND<br>Patient must have at least one of:<br>(i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth; AND<br>The treatment must be administered no earlier than at 16 weeks gestation. | Compliance with Authority Required procedures - Streamlined Authority Code 11673 |
| C11680 | P11680 | CN11680 | Sacubitril with valsartan | Chronic heart failure<br>Patient must be symptomatic with NYHA classes II, III or IV; AND<br>Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND<br>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:<br>(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<br>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<br>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<br>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)<br>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 | Compliance with Authority Required procedures |

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| | | | | The treatment must be as adjunctive therapy to at least two other anti-epileptic drugs; AND<br>Must be treated by a neurologist if treatment is being initiated. or<br>Must be treated by a neurologist if treatment is being continued or re-initiated. or<br>Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued. or<br>Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued. | |
| C11683 | P11683 | CN11683 | Clonazepam<br>Haloperidol<br>Metoclopramide | For use in patients receiving palliative care | |
| C11696 | P11696 | CN11696 | Fentanyl<br>Methadone | Severe disabling pain<br>Patient must not be opioid naive; AND<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; AND<br>Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| C11697 | P11697 | CN11697 | Hydromorphone<br>Morphine | Severe pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or<br>Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; AND<br>Patient must be undergoing palliative care. | Compliance with Authority Required procedures - Streamlined Authority Code 11697 |
| C11699 | P11699 | CN11699 | Midostaurin | Acute Myeloid Leukaemia<br>Maintenance therapy - Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures |

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| | | | | Patient must not be undergoing or have undergone a stem cell transplant.<br>A maximum of 9 cycles will be authorised under this restriction in a lifetime.<br>Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.<br>If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.<br>Progressive disease is defined as the presence of any of the following:<br>Leukaemic cells in the CSF;<br>Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;<br>Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;<br>Extramedullary leukaemia.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | |
| C11704 | P11704 | CN11704 | Adalimumab | Severe Crohn disease<br>First continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(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 | Compliance with Authority Required procedures |

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| | | | | level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C11709 | P11709 | CN11709 | Adalimumab | Severe Crohn disease<br>Balance of supply<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or<br>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<br>The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment. or<br>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<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND | Compliance with Authority Required procedures |

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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug 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.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity | |

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| | | | | resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.<br>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. | |
| C11713 | P11713 | CN11713 | Adalimumab | Severe Crohn disease<br>Balance of supply for paediatric patient<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or<br>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<br>The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; or<br>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<br>Must be treated by a gastroenterologist (code 87). or | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or<br>Must be treated by a paediatrician. or<br>Must be treated by a specialist paediatric gastroenterologist. | |
| C11715 | P11715 | CN11715 | Adalimumab | Severe Crohn disease<br>Initial treatment - Initial 1 (new patient)<br>Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence; AND<br>Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:<br>(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<br>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<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 6 to 17 years inclusive;<br>Must be treated by a gastroenterologist (code 87). or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a paediatrician. or<br>Must be treated by a specialist paediatric gastroenterologist.<br>The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>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).<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | |
| C11716 | P11716 | CN11716 | Adalimumab | Severe Crohn disease<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>Patient must have 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 | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 6 to 17 years inclusive;<br>Must be treated by a gastroenterologist (code 87). or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or<br>Must be treated by a paediatrician. or<br>Must be treated by a specialist paediatric gastroenterologist.<br>The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The PCDAI assessment must be no more than 4 weeks old at the time of application.<br>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.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11717 | P11717 | CN11717 | Adalimumab | Severe Crohn disease<br>Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI<br>Patient must have a documented history of severe Crohn disease; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND<br>Patient must have a total PCDAI score of 40 points or less; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 6 to 17 years inclusive;<br>Must be treated by a gastroenterologist (code 87). or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or<br>Must be treated by a paediatrician. or<br>Must be treated by a specialist paediatric gastroenterologist.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The PCDAI assessment must be no more than 4 weeks old at the time of application.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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.<br>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. | |
| C11718 | P11718 | CN11718 | Adalimumab | Severe Crohn disease<br>Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI<br>Patient must have a documented history of severe Crohn disease; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND<br>Patient must have a total PCDAI score of 40 points or less; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 6 to 17 years inclusive;<br>Must be treated by a gastroenterologist (code 87). or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or<br>Must be treated by a paediatrician. or<br>Must be treated by a specialist paediatric gastroenterologist.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>The PCDAI assessment must be no more than 4 weeks old at the time of application.<br>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 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11746 | P11746 | CN11746 | Clonazepam | For use in patients receiving palliative care | |
| C11753 | P11753 | CN11753 | Buprenorphine<br>Morphine<br>Oxycodone<br>Oxycodone with naloxone | Severe disabling pain<br>Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; or<br>Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance; AND<br>Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| C11755 | P11755 | CN11755 | Obinutuzumab | Follicular lymphoma<br>Re-induction treatment<br>Patient must not have previously received PBS-subsidised obinutuzumab; AND<br>The condition must be CD20 positive; AND<br>The condition must be refractory to treatment with rituximab for this condition; AND<br>The condition must be symptomatic; AND<br>The treatment must be for re-induction treatment purposes only; AND<br>The treatment must be in combination with bendamustine; AND<br>The treatment must not exceed 8 doses for re-induction treatment with this drug for this condition.<br>The condition is considered rituximab-refractory if the patient experiences less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.<br>A patient may only qualify for PBS-subsidised initiation treatment once in a lifetime under<br>i) the previously untreated induction treatment restriction; or<br>ii) the rituximab-refractory re-induction restriction. | Compliance with Authority Required procedures |
| C11759 | P11759 | CN11759 | Adalimumab | Severe Crohn disease<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>Where 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.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11761 | P11761 | CN11761 | Adalimumab | Severe Crohn disease<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have a documented history of severe Crohn disease; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 6 to 17 years inclusive;<br>Must be treated by a gastroenterologist (code 87). or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or<br>Must be treated by a paediatrician. or<br>Must be treated by a specialist paediatric gastroenterologist.<br>The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11762 | P11762 | CN11762 | Adalimumab | Severe Crohn disease<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];<br>Patient must be aged 18 years or older;<br>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<br>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<br>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<br>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<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction; AND<br>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<br>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<br>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 | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following<br>(a) patient must have evidence of intestinal inflammation;<br>(b) patient must be assessed clinically as being in a high faecal output state;<br>(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.<br>(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<br>(ii) faeces higher than normal lactoferrin or calprotectin level; or<br>(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.<br>Evidence of intestinal inflammation includes<br>(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<br>(ii) faeces higher than normal lactoferrin or calprotectin level; or<br>(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.<br>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. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>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.<br>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.<br>Details of the accepted toxicities including severity can be found on the Services Australia website.<br>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.<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C11763 | P11763 | CN11763 | Adalimumab | Severe Crohn disease<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>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<br>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<br>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<br>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<br>Patient must have evidence of intestinal inflammation; or<br>Patient must be assessed clinically as being in a high faecal output state; or<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Evidence of intestinal inflammation includes<br>(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<br>(ii) faeces higher than normal lactoferrin or calprotectin level; or<br>(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.<br>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.<br>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.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11767 | P11767 | CN11767 | Adalimumab | Severe Crohn disease<br>First continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI<br>Patient must have a documented history of severe Crohn disease; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND<br>Patient must have a total PCDAI score of 40 points or less; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 6 to 17 years inclusive;<br>Must be treated by a gastroenterologist (code 87). or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. or<br>Must be treated by a paediatrician. or<br>Must be treated by a specialist paediatric gastroenterologist.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The PCDAI assessment must be no more than 4 weeks old at the time of application.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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.<br>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. | |
| C11784 | P11784 | CN11784 | Botulinum toxin type A purified neurotoxin complex | Chronic migraine<br>Must be treated by a neurologist; AND<br>Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin; AND<br>Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin; AND<br>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<br>Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin;<br>Patient must be aged 18 years or older.<br>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<br>Maintenance therapy<br>Patient must have previously received PBS-subsidised treatment with this drug under the rituximab refractory initial restriction; AND<br>The condition must be CD20 positive; AND<br>The condition must have been refractory to treatment with rituximab; AND<br>Patient must have demonstrated a partial or complete response to PBS-subsidised re-induction treatment with this drug for this condition; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must be maintenance therapy; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | |
| C11787 | P11787 | CN11787 | Obinutuzumab | Stage II bulky or Stage III/IV follicular lymphoma<br>Maintenance therapy<br>Patient must have previously received PBS-subsidised treatment with this drug under the previously untreated initial restriction; AND<br>The condition must be CD20 positive; AND<br>Patient must have demonstrated a partial or complete response to PBS subsidised induction treatment with this drug for this condition; AND<br>The treatment must be maintenance therapy; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C11815 | P11815 | CN11815 | Obinutuzumab | Stage II bulky or Stage III/IV follicular lymphoma<br>Induction treatment<br>The condition must be CD20 positive; AND<br>The condition must be previously untreated; AND<br>The condition must be symptomatic; AND<br>The treatment must be for induction treatment purposes only; AND<br>The treatment must be in combination with chemotherapy; AND<br>The treatment must not exceed 10 doses for induction treatment with this drug for this condition.<br>A patient may only qualify for PBS-subsidised initiation treatment once in a lifetime under<br>i) the previously untreated induction treatment restriction; or | Compliance with Authority Required procedures |

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| | | | | ii) the rituximab-refractory re-induction restriction. | |
| C11826 | P11826 | CN11826 | Infliximab | Moderate to severe ulcerative colitis<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; or<br>Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or<br>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form;<br>Patient must be aged 18 years or older.<br>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This | Compliance with Authority Required procedures |

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| | | | | will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11834 | P11834 | CN11834 | Ixekizumab | Severe psoriatic arthritis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or<br>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND | Compliance with Written Authority Required procedures |

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| | | | | The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the | |

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| | | | | most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C11835 | P11835 | CN11835 | Progesterone | Prevention of preterm birth<br>Patient must have a singleton pregnancy; AND<br>Patient must have at least one of:<br>(i) short cervix (mid-trimester sonographic cervix no greater than 25 mm), (ii) a history of spontaneous preterm birth; AND<br>The treatment must be administered no earlier than at 16 weeks gestation. | Compliance with Authority Required procedures - Streamlined Authority Code 11835 |
| C11836 | P11836 | CN11836 | Sapropterin | Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)<br>Pre-conception through to when pregnancy first becomes known<br>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<br>Must be treated by a metabolic physician; or<br>Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND<br>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<br>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);<br>Patient must be actively trying to conceive. | Compliance with Authority Required procedures |

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| C11838 | P11838 | CN11838 | Testosterone | Constitutional delay of growth or puberty<br>Patient must be under 18 years of age;<br>Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists; AND<br>The treatment must be applied to the scrotum area.<br>The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C11841 | P11841 | CN11841 | Benralizumab<br>Mepolizumab<br>Omalizumab | Uncontrolled severe asthma<br>Balance of supply<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; or<br>Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; or<br>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction. or<br>The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction. | Compliance with Authority Required procedures |
| C11842 | P11842 | CN11842 | Benralizumab<br>Mepolizumab | Uncontrolled severe asthma<br>Continuing treatment<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND | Compliance with Written Authority Required procedures |

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

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| | | | | time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.<br>A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.<br>At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Severe Asthma Continuing PBS Authority Application - Supporting Information Form which includes<br>(i) details of maintenance oral corticosteroid dose; or<br>(ii) a completed Asthma Control Questionnaire (ACQ-5) score. | |
| C11844 | P11844 | CN11844 | Dupilumab | Uncontrolled severe asthma<br>Initial treatment - Initial 2 (Change of treatment)<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must be under the care of the same physician for at least 6 months; or<br>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND<br>Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; or<br>Patient must have each of:<br>i) total serum human immunoglobulin E greater than or equal to 30 IU/mL | Compliance with Authority Required procedures |

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| | | | | measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, ii) past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND<br>Patient must have received regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation; AND<br>Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:<br>(i) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and<br>(iii) eosinophil count and date; and<br>(iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); or<br>(v) the IgE results; and<br>(vi) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the | |

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| | | | | patient will be deemed to have failed to respond to treatment with that previous biological medicine.<br>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine.<br>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator. | |
| C11846 | P11846 | CN11846 | Omalizumab | Uncontrolled severe asthma<br>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must be under the care of the same physician for at least 6 months; or<br>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; or | Compliance with Authority Required procedures |

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| | | | | Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND<br>Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features:<br>(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; or<br>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND<br>Patient must have a duration of asthma of at least 1 year; AND<br>Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old at the time of application; AND<br>Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL; AND<br>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND<br>Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>Optimised asthma therapy includes<br>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;<br>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg | |

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| | | | | prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.<br>AND<br>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.<br>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.<br>The initial IgE assessment must be no more than 12 months old at the time of application.<br>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:<br>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND<br>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.<br>(a) a completed authority prescription form; and<br>(b) a completed Severe Asthma PBS Authority Application - Supporting Information Form,<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the IgE result; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score.<br>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral | |

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| | | | | corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.<br>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle.<br>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.<br>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.<br>At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and | |

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| | | | | (b) a completed Severe Asthma PBS Authority Application - Supporting Information Form,<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the IgE result; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score.<br>which includes the following:<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the IgE result; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score. | |
| C11847 | P11847 | CN11847 | Omalizumab | Uncontrolled severe asthma<br>Continuing treatment<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 12 years or older.<br>An adequate response to omalizumab treatment is defined as<br>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR<br>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR | Compliance with Written Authority Required procedures |

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| | | | | (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).<br>All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate must be made at around 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug.<br>Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.<br>A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.<br>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed Severe Asthma PBS Authority Application and Supporting Information Form which includes details of | |

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| | | | | (i) maintenance oral corticosteroid dose; or<br>(ii) Asthma Control Questionnaire (ACQ-5) score including the date of assessment of the patient's symptoms; or<br>(iii) for patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the exacerbation rate has reduced. | |
| C11848 | P11848 | CN11848 | Mepolizumab | Uncontrolled severe asthma<br>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must be under the care of the same physician for at least 6 months; or<br>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; or<br>Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND<br>Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features:<br>(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; or<br>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND<br>Patient must have a duration of asthma of at least 1 year; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; or<br>Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND<br>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND<br>Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>Optimised asthma therapy includes<br>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;<br>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.<br>AND<br>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.<br>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.<br>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND<br>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.<br>(a) a completed authority prescription form; and<br>(b) a completed Severe Asthma Initial PBS Authority Application - Supporting Information Form,<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score.<br>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.<br>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.<br>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.<br>At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Severe Asthma Initial PBS Authority Application - Supporting Information Form,<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score.<br>which includes the following:<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score. | |
| C11852 | P11852 | CN11852 | Adalimumab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a gastroenterologist (code 87); or | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND<br>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or<br>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or<br>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (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<br>Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or<br>Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years;<br>Patient must be 6 years of age or older.<br>The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes<br>(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and<br>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.<br>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.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>Details of the accepted toxicities including severity can be found on the Services Australia website. | |
| C11853 | P11853 | CN11853 | Adalimumab | Moderate to severe ulcerative colitis<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or<br>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;<br>Patient must be 6 years of age or older.<br>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.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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. | |
| C11854 | P11854 | CN11854 | Adalimumab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; or<br>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<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; or<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years;<br>Patient must be 6 years of age or older.<br>The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes<br>(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.<br>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. | |
| C11855 | P11855 | CN11855 | Adalimumab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or<br>Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years;<br>Patient must be 6 years of age or older. | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The authority application must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes<br>(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.<br>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.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>Details of the accepted toxicities including severity can be found on the Services Australia website. | |
| C11861 | P11861 | CN11861 | Adalimumab | Severe psoriatic arthritis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11865 | P11865 | CN11865 | Adalimumab | Severe psoriatic arthritis<br>Subsequent continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An 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. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug 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.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11867 | P11867 | CN11867 | Adalimumab | Severe psoriatic arthritis<br>First continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50% | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11875 | P11875 | CN11875 | Sunitinib | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Continuing treatment beyond 3 months<br>Patient must have received an initial authority prescription for this drug for this condition; AND | Compliance with Authority Required procedures - |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of (i) cabozantinib, (ii) pazopanib, (iii) sunitinib. | Streamlined Authority Code 11875 |
| C11878 | P11878 | CN11878 | Sunitinib | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Initial treatment<br>The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of (i) cabozantinib, (ii) pazopanib, (iii) sunitinib. | Compliance with Authority Required procedures - Streamlined Authority Code 11878 |
| C11880 | P11880 | CN11880 | Cabozantinib | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Initial treatment<br>The condition must be each of:<br>(i) classified as having an intermediate to poor survival risk score according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), (ii) untreated with a tyrosine kinase inhibitor; or<br>Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) despite treatment with a tyrosine kinase inhibitor, irrespective of the current IMDC survival risk score; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must be undergoing treatment with this drug for the first time at the time of the first PBS prescription. | Compliance with Authority Required procedures - Streamlined Authority Code 11880 |

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| C11883 | P11883 | CN11883 | Tofacitinib | Moderate to severe ulcerative colitis<br>Continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug;<br>Patient must be aged 18 years or older.<br>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11886 | P11886 | CN11886 | Tofacitinib<br>Upadacitinib | Severe psoriatic arthritis<br>Continuing treatment - balance of supply<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C11890 | P11890 | CN11890 | Guselkumab | Severe psoriatic arthritis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.<br>Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11891 | P11891 | CN11891 | Testosterone | Androgen deficiency<br>Patient must not have an established pituitary or testicular disorder; AND<br>The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs;<br>Patient must be aged 40 years or older;<br>Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists; AND<br>The treatment must be applied to the scrotum area.<br>Androgen deficiency is defined as | Compliance with Authority Required procedures |

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| | | | | (i) testosterone level of less than 6 nmol per litre; OR<br>(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).<br>Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.<br>The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.<br>The name of the specialist must be included in the authority application. | |
| C11892 | P11892 | CN11892 | Benralizumab | Uncontrolled severe asthma<br>Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must be under the care of the same physician for at least 6 months; or<br>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; or<br>Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND<br>Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features:<br>(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; or<br>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND<br>Patient must have a duration of asthma of at least 1 year; AND<br>Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; or<br>Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; AND<br>Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND<br>Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>Optimised asthma therapy includes<br>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;<br>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.<br>AND<br>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.<br>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.<br>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:<br>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND<br>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.<br>(a) a completed authority prescription form; and<br>(b) a completed Severe Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score.<br>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.<br>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.<br>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.<br>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator.<br>At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Severe Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; and<br>(iv) Asthma Control Questionnaire (ACQ-5) score. | |
| C11893 | P11893 | CN11893 | Benralizumab | Uncontrolled severe asthma<br>Initial treatment - Initial 2 (Change of treatment) | Compliance with Authority Required procedures |

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| | | | | Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND | |
| | | | | Patient must be under the care of the same physician for at least 6 months; or | |
| | | | | Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND | |
| | | | | Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND | |
| | | | | Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND | |
| | | | | Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; or | |
| | | | | Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND | |
| | | | | Patient must not receive more than 32 weeks of treatment under this restriction; AND | |
| | | | | The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; | |
| | | | | Patient must be aged 12 years or older. | |
| | | | | The authority application must be made in writing and must include: | |
| | | | | (a) a completed authority prescription form; and | |
| | | | | (b) a completed Severe Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following: | |
| | | | | (i) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and | |
| | | | | (ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and | |
| | | | | (iii) eosinophil count and date; and | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and<br>(v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.<br>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug.<br>At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator. | |

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| C11897 | P11897 | CN11897 | Dupilumab | Uncontrolled severe asthma<br>Initial treatment - Initial 2 (Change of treatment)<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must be under the care of the same physician for at least 6 months; or<br>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND<br>Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; or<br>Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; or<br>Patient must have had a total serum human immunoglobulin E greater than or equal to 30 IU/mL with a past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND<br>Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following: | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (i) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and<br>(iii) eosinophil count and date; and<br>(iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); or<br>(v) the IgE results; and<br>(vi) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.<br>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine.<br>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of | |

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| | | | | therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator. | |
| C11902 | P11902 | CN11902 | Omalizumab | Uncontrolled severe asthma<br>Initial treatment - Initial 2 (Change of treatment)<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must be under the care of the same physician for at least 6 months; or<br>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND<br>Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND<br>Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma; AND<br>Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Severe Asthma (omalizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following: | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (i) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and<br>(iii) the IgE results; and<br>(iv) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.<br>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine.<br>At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator. | |

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| C11903 | P11903 | CN11903 | Adalimumab | Moderate to severe ulcerative colitis<br>First continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or<br>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;<br>Patient must be 6 years of age or older.<br>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.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>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.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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. | |
| C11906 | P11906 | CN11906 | Adalimumab | Severe psoriatic arthritis<br>Continuing treatment - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or<br>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<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND<br>Must be treated by a rheumatologist. or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
| C11910 | P11910 | CN11910 | Infliximab | Severe Crohn disease<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received this drug (in any form) as their most recent course of PBS-subsidised biological medicine treatment for this condition; or<br>Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab intravenous form continuing treatment restriction; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form;<br>Patient must be aged 18 years or older.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and<br>(iii) the date of clinical assessment.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted up to 12 weeks of therapy and no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11915 | P11915 | CN11915 | Tofacitinib | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | |
| C11917 | P11917 | CN11917 | Guselkumab | Severe psoriatic arthritis<br>Continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy.<br>Where an assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11918 | P11918 | CN11918 | Guselkumab<br>Ixekizumab | Severe psoriatic arthritis<br>Continuing treatment - balance of supply<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11919 | P11919 | CN11919 | Guselkumab | Severe psoriatic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND<br>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or<br>Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.<br>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and<br>either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list of major joints<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). | Compliance with Written Authority Required procedures |

Clause 1

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| | | | | If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |
| C11924 | P11924 | CN11924 | Dupilumab | Uncontrolled severe asthma<br>Continuing treatment<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 12 years or older.<br>An adequate response to this biological medicine is defined as<br>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,<br>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.<br>OR<br>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.<br>All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made at around 20 weeks after the first dose of PBS-subsidised | Compliance with Authority Required procedures |

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| | | | | dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.<br>The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug.<br>Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.<br>A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.<br>A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.<br>At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Uncontrolled severe asthma adolescent and adult continuing PBS authority application form which includes<br>(i) details of maintenance oral corticosteroid dose; or<br>(ii) a completed Asthma Control Questionnaire (ACQ-5) score. | |
| C11926 | P11926 | CN11926 | Dupilumab | Uncontrolled severe asthma<br>Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy) | Compliance with Authority Required procedures |

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| | | | | Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must be under the care of the same physician for at least 6 months; or<br>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; or<br>Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND<br>Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features:<br>(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; or<br>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND<br>Patient must have a duration of asthma of at least 1 year; AND<br>Patient must have been receiving regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation; AND<br>Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; or<br>Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that is no more than 1 year old; AND | |

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| | | | | Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND<br>Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>Optimised asthma therapy includes<br>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;<br>(ii) treatment with oral corticosteroids as outlined in the clinical criteria.<br>AND<br>(ii) treatment with oral corticosteroids as outlined in the clinical criteria.<br>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.<br>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:<br>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND<br>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.<br>(a) a completed authority prescription form; and<br>(b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and | |

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| | | | | (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; or<br>(iv) the IgE result; and<br>(v) Asthma Control Questionnaire (ACQ-5) score.<br>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break..<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.<br>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.<br>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.<br>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator.<br>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of | |

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| | | | | therapy, at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Uncontrolled severe asthma - adolescent and adult initial PBS authority application form, which includes the following:<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; or<br>(iv) the IgE result; and<br>(v) Asthma Control Questionnaire (ACQ-5) score. | |
| C11930 | P11930 | CN11930 | Ipilimumab | Unresectable malignant mesothelioma<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be in combination with PBS-subsidised nivolumab for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must not exceed a maximum total of 24 months in a lifetime for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 11930 |
| C11937 | P11937 | CN11937 | Pazopanib | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Continuing treatment beyond 3 months<br>Patient must have received an initial authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 11937 |

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| | | | | 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. | |
| C11939 | P11939 | CN11939 | Pazopanib | Stage IV clear cell variant renal cell carcinoma (RCC)<br>Continuing treatment beyond 3 months<br>Patient must have received an initial authority prescription for this drug for this condition; AND<br>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND<br>Patient must require dose adjustment; AND<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of (i) cabozantinib, (ii) pazopanib, (iii) sunitinib. | Compliance with Authority Required procedures - Streamlined Authority Code 11939 |
| C11940 | P11940 | CN11940 | Tofacitinib | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND<br>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or | Compliance with Written Authority Required procedures |

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

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.<br>A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | |
| C11944 | P11944 | CN11944 | Tofacitinib<br>Upadacitinib | Severe psoriatic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND<br>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or<br>Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.<br>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and<br>either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list of major joints<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11945 | P11945 | CN11945 | Tofacitinib<br>Upadacitinib | Severe psoriatic arthritis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11947 | P11947 | CN11947 | Testosterone | Micropenis<br>Patient must be under 18 years of age;<br>Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists; AND<br>The treatment must be applied to the scrotum area.<br>The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C11950 | P11950 | CN11950 | Mepolizumab | Uncontrolled severe asthma<br>Initial treatment - Initial 2 (Change of treatment)<br>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND<br>Patient must be under the care of the same physician for at least 6 months; or<br>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle; AND<br>Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; or<br>Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; AND<br>Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Severe Asthma (mepolizumab/benralizumab) Initial PBS Authority Application - Supporting Information Form, which includes the following:<br>(i) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment; and | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (iii) eosinophil count and date; and<br>(iv) the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and<br>(v) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.<br>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug.<br>At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and<br>A pharmacist, nurse or asthma educator. | |
| C11956 | P11956 | CN11956 | Tofacitinib<br>Upadacitinib | Severe psoriatic arthritis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a rheumatologist; or | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or<br>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND<br>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C11958 | P11958 | CN11958 | Ixekizumab | Severe psoriatic arthritis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11959 | P11959 | CN11959 | Ixekizumab | Severe psoriatic arthritis<br>Continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or | Compliance with Written Authority Required procedures |

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| | | | | (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11960 | P11960 | CN11960 | Sapropterin | Maternal hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)<br>Existing pregnancy to birth<br>Patient must be pregnant;<br>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 | Compliance with Authority Required procedures |

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| | | | | phenylalanine levels from baseline during initial responsiveness testing of no less than 30%; AND<br>Must be treated by a metabolic physician; or<br>Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician; AND<br>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<br>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). | |
| C11962 | P11962 | CN11962 | Testosterone | Androgen deficiency<br>Patient must have an established pituitary or testicular disorder; AND<br>Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists; AND<br>The treatment must be applied to the scrotum area.<br>The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C11963 | P11963 | CN11963 | Testosterone | Pubertal induction<br>Patient must be under 18 years of age;<br>Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists; AND<br>The treatment must be applied to the scrotum area.<br>The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C11964 | P11964 | CN11964 | Dupilumab | Uncontrolled severe asthma<br>Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy) | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma; AND | |
| | | | | Patient must be under the care of the same physician for at least 6 months; or | |
| | | | | Patient must have been diagnosed by a multidisciplinary severe asthma clinic team; AND | |
| | | | | Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; or | |
| | | | | Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma; AND | |
| | | | | Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features:<br>(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; or | |
| | | | | Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND | |
| | | | | Patient must have a duration of asthma of at least 1 year; AND | |
| | | | | Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months; or | |
| | | | | Patient must have blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; or | |
| | | | | Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the last 12 months; AND | |
| | | | | Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not receive more than 32 weeks of treatment under this restriction; AND<br>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma;<br>Patient must be aged 12 years or older.<br>Optimised asthma therapy includes<br>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;<br>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.<br>AND<br>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.<br>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.<br>The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:<br>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND<br>(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.<br>(a) a completed authority prescription form; and | |

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| | | | | (b) a completed Severe asthma - adolescent and adult initial PBS authority application form, which includes the following:<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; or<br>(iv) the IgE result; and<br>(v) Asthma Control Questionnaire (ACQ-5) score.<br>The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.<br>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the date of assessment. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.<br>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.<br>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.<br>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.<br>A multidisciplinary severe asthma clinic team comprises of:<br>A respiratory physician; and | |

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| | | | | A pharmacist, nurse or asthma educator.<br>At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Severe asthma - adolescent and adult initial PBS authority application form, which includes the following:<br>(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and<br>(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and<br>(iii) the eosinophil count and date; or<br>(iv) the IgE result; and<br>(v) Asthma Control Questionnaire (ACQ-5) score. | |
| C11966 | P11966 | CN11966 | Adalimumab | Moderate to severe ulcerative colitis<br>Continuing treatment - balance of supply<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>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<br>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)<br>Initial treatment | Compliance with Authority Required |

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| | | | | The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.<br>PBS-subsidy does not apply to a patient who has progressive disease whilst on, or, who has recurrent disease following treatment with any of (i) cabozantinib, (ii) pazopanib, (iii) sunitinib. | procedures - Streamlined Authority Code 11974 |
| C11975 | P11975 | CN11975 | Tofacitinib | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>Patient must have a Mayo clinic score greater than or equal to 6; or<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and | Compliance with Written Authority Required procedures |

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| | | | | (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.<br>An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | |
| C11976 | P11976 | CN11976 | Tofacitinib<br>Upadacitinib | Moderate to severe ulcerative colitis<br>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or | Compliance with Authority Required procedures |

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| | | | | Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | |
| C11978 | P11978 | CN11978 | Tofacitinib<br>Upadacitinib | Severe psoriatic arthritis<br>Continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and<br>either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.<br>The authority application must be made in writing and must include | Compliance with Written Authority Required procedures |

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| | | | | (a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C11979 | P11979 | CN11979 | Guselkumab | Severe psoriatic arthritis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or | Compliance with Written Authority Required procedures |

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| | | | | The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND<br>The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |
| C11981 | P11981 | CN11981 | Ixekizumab | Severe psoriatic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND<br>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND | Compliance with Written Authority Required procedures |

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| | | | | Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND<br>Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or<br>Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND<br>Patient must not receive more than 20 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.<br>The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and<br>either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list of major joints<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |

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| | | | | An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C11985 | P11985 | CN11985 | Nivolumab | Unresectable malignant mesothelioma<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be in combination with PBS-subsidised ipilimumab, unless an intolerance to ipilimumab of a severity necessitating permanent treatment withdrawal of ipilimumab; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must not exceed a maximum total of 24 months in a lifetime for this condition.<br>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 11985 |
| C11999 | P11999 | CN11999 | Teduglutide | Type III Short bowel syndrome with intestinal failure<br>Initial treatment - balance of supply<br>Must be treated by a gastroenterologist; or<br>Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit; AND<br>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND<br>Patient must have received insufficient therapy with this drug under the initial treatment restriction to complete the maximum duration of 12 months of initial treatment; AND | Compliance with Authority Required procedures |

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| | | | | The treatment must provide no more than the balance of up to 12 months of treatment. | |
| C12003 | P12003 | CN12003 | Infliximab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; or<br>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<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; or<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years;<br>Patient must be 6 years of age or older.<br>Application for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment. | Compliance with Written Authority Required procedures |

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| | | | | A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.<br>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.<br>Up to a maximum of 2 repeats will be authorised.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this | |

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| | | | | 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.<br>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. | |
| C12004 | P12004 | CN12004 | Infliximab | Severe active rheumatoid arthritis<br>Subsequent continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>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<br>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<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction; AND<br>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following active joints, from at least 4, by at least 50% | Compliance with Written Authority Required procedures |

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| | | | | (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.<br>Up to a maximum of 2 repeats will be authorised.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and<br>(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.<br>The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed within 4 weeks prior to completing their current course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | |
| C12016 | P12016 | CN12016 | Cetuximab | Metastatic colorectal cancer<br>Continuing treatment | Compliance with Authority Required |

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| | | | | Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; or<br>Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC; AND<br>Patient must not have progressive disease; AND<br>The treatment must be as monotherapy; or<br>The treatment must be in combination with chemotherapy; AND<br>The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.<br>Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab.<br>Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab. | procedures - Streamlined Authority Code 12016 |
| C12025 | P12025 | CN12025 | Infliximab | Severe Crohn disease<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>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<br>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<br>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or | Compliance with Written Authority Required procedures |

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| | | | | Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed Crohn Disease Activity Index (CDAI) Score; or<br>(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and<br>(iii) the date of the most recent clinical assessment.<br>All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.<br>Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was | |

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| | | | | approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request 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.<br>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period. | |
| C12029 | P12029 | CN12029 | Eptinezumab<br>Galcanezumab | Chronic migraine<br>Continuing treatment<br>Must be treated by a specialist neurologist or in consultation with a specialist neurologist; AND<br>Patient must not be undergoing concurrent treatment with the following PBS benefits:<br>(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<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of migraine days per month; AND<br>Patient must continue to be appropriately managed for medication overuse headache.<br>Patient must have the number of migraine days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12029 |
| C12035 | P12035 | CN12035 | Panitumumab | Metastatic colorectal cancer<br>Continuing treatment | Compliance with Authority Required procedures - |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of first-line chemotherapy; or<br>Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC; AND<br>Patient must not have progressive disease; AND<br>The treatment must be as monotherapy; or<br>The treatment must be in combination with chemotherapy; AND<br>The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.<br>Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.<br>Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab. | Streamlined Authority Code 12035 |
| C12042 | P12042 | CN12042 | Infliximab | Moderate to severe ulcerative colitis<br>Continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or<br>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<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or | Compliance with Authority Required procedures - Streamlined Authority Code 12042 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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;<br>Patient must be 6 years of age or older.<br>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.<br>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.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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. | |
| C12043 | P12043 | CN12043 | Infliximab | Severe Crohn disease<br>First continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or<br>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 | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or<br>(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and<br>(iii) the date of clinical assessment.<br>All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>At the time of the authority application, medical practitioners should request 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.<br>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period. | |
| C12045 | P12045 | CN12045 | Cetuximab | Metastatic colorectal cancer<br>Initial treatment<br>Patient must have RAS wild-type metastatic colorectal cancer; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The condition must have failed to respond to first-line chemotherapy; or<br>The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC; AND<br>The treatment must be as monotherapy; or<br>The treatment must be in combination with chemotherapy; AND<br>The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.<br>Patients who have progressive disease on panitumumab are not eligible to receive PBS-subsidised cetuximab. | Compliance with Authority Required procedures - Streamlined Authority Code 12045 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patients who have developed intolerance to panitumumab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised cetuximab. | |
| C12049 | P12049 | CN12049 | Infliximab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or<br>Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; or<br>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);<br>Patient must be 6 years of age or older.<br>Application for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>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.<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.<br>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.<br>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.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>Details of the accepted toxicities including severity can be found on the Services Australia website.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C12051 | P12051 | CN12051 | Infliximab | Severe Crohn disease<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>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<br>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 | Compliance with Authority Required procedures - Streamlined Authority Code 12051 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12059 | P12059 | CN12059 | Infliximab | Moderate to severe ulcerative colitis<br>Continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or<br>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<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or<br>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;<br>Patient must be 6 years of age or older.<br>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.<br>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.<br>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.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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. | |
| C12063 | P12063 | CN12063 | Infliximab | Severe Crohn disease<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction;<br>Patient must be aged 18 years or older.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following<br>(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and<br>(iii) the date of clinical assessment; and<br>(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.<br>If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.<br>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.<br>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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. | |
| C12064 | P12064 | CN12064 | Galcanezumab | Chronic migraine<br>Initial treatment<br>Must be treated by a neurologist; AND<br>Patient must not be undergoing concurrent treatment with the following PBS benefits:<br>(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<br>Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with this medicine for this condition; AND<br>Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with this drug for this condition; AND<br>Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with this drug;<br>Patient must be aged 18 years or older.<br>Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.<br>Patient must have the number of migraine days per month documented in their medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12064 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C12066 | P12066 | CN12066 | Panitumumab | Metastatic colorectal cancer<br>Initial treatment<br>Patient must have RAS wild-type metastatic colorectal cancer; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>The condition must have failed to respond to first-line chemotherapy; or<br>The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC; AND<br>The treatment must be as monotherapy; or<br>The treatment must be in combination with chemotherapy; AND<br>The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition.<br>Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab.<br>Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab. | Compliance with Authority Required procedures - Streamlined Authority Code 12066 |
| C12069 | P12069 | CN12069 | Infliximab | Severe Crohn disease<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>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<br>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<br>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or | Compliance with Authority Required procedures - Streamlined Authority Code 12069 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12074 | P12074 | CN12074 | Infliximab | Moderate to severe ulcerative colitis<br>Continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or | Compliance with Authority Required procedures - Streamlined Authority Code 12074 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or<br>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;<br>Patient must be 6 years of age or older.<br>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.<br>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.<br>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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. | |
| C12078 | P12078 | CN12078 | Vedolizumab | Moderate to severe ulcerative colitis<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or<br>Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; or<br>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>Up to a maximum of 5 repeats will be authorised.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | |

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| | | | | If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12080 | P12080 | CN12080 | Vedolizumab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND<br>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or<br>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or<br>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND<br>Patient must have a Mayo clinic score greater than or equal to 6; or | Compliance with Written Authority Required procedures |

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| | | | | Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Application for authorisation of initial treatment must be in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and<br>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].<br>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.<br>A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.<br>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is | |

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| | | | | not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>Details of the accepted toxicities including severity can be found on the Services Australia website. | |
| C12083 | P12083 | CN12083 | Vedolizumab | Severe Crohn disease<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];<br>Patient must be aged 18 years or older;<br>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<br>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<br>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<br>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 | Compliance with Written Authority Required procedures |

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| | | | | 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<br>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment; AND<br>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<br>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<br>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.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and<br>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and<br>(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and<br>(iv) the date of the most recent clinical assessment.<br>Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following<br>(a) patient must have evidence of intestinal inflammation;<br>(b) patient must be assessed clinically as being in a high faecal output state; | |

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| | | | | (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.<br>(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<br>(ii) faeces higher than normal lactoferrin or calprotectin level; or<br>(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.<br>Evidence of intestinal inflammation includes<br>(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<br>(ii) faeces higher than normal lactoferrin or calprotectin level; or<br>(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.<br>All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment<br>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.<br>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.<br>Details of the accepted toxicities including severity can be found on the Services Australia website.<br>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must | |

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| | | | | be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.<br>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.<br>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C12084 | P12084 | CN12084 | Obeticholic acid | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)<br>Initial treatment<br>Must be treated by a prescriber who is either:<br>(i) a gastroenterologist, (ii) a hepatologist; or<br>Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND<br>Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; or | Compliance with Authority Required procedures |

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| | | | | Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated; AND<br>Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; or<br>Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug; AND<br>Patient must not have/be each of:<br>(i) severe liver disease, (ii) immunocompromised; AND<br>Patient must have an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) having accounted for each of:<br>(i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; or<br>Patient must have a total bilirubin level between 1 to 2 times the ULN, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; or<br>Patient must have abnormal readings of at least one of:<br>(i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid;<br>Patient must be aged 18 years or older.<br>Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction. | |
| C12096 | P12096 | CN12096 | High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate | Ketogenic diet<br>Patient must be undergoing treatment under the strict supervision of a dietitian, together with at least one of:<br>(i) a metabolic physician, (ii) a neurologist; AND<br>Patient must have intractable seizures requiring treatment with a ketogenic diet. or<br>Patient must have a glucose transport protein defect. or<br>Patient must have pyruvate dehydrogenase deficiency. | |

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| C12098 | P12098 | CN12098 | Adalimumab | Complex refractory Fistulising Crohn disease<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>Applications for authorisation must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following<br>(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and<br>(ii) details of prior biological medicine treatment including details of date and duration of treatment.<br>The most recent fistula assessment must be no more than 4 weeks old at the time of application. | Compliance with Written Authority Required procedures |

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| | | | | A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | |
| C12101 | P12101 | CN12101 | Adalimumab | Complex refractory Fistulising Crohn disease<br>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<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must 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<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C12103 | P12103 | CN12103 | Adalimumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist. | Compliance with Written Authority Required procedures |

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| | | | | The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |
| C12105 | P12105 | CN12105 | Adalimumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:<br>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; | Compliance with Written Authority Required procedures |

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| | | | | or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes 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.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |

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| C12120 | P12120 | CN12120 | Adalimumab | Severe active juvenile idiopathic arthritis<br>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<br>Must be treated by a paediatric rheumatologist; or<br>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C12122 | P12122 | CN12122 | Adalimumab | Severe active juvenile idiopathic arthritis<br>First continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as | Compliance with Written Authority Required procedures |

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| | | | | an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or<br>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or<br>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder, 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).<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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. | |
| C12123 | P12123 | CN12123 | Adalimumab | Severe active juvenile idiopathic arthritis<br>Continuing treatment - balance of supply<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or<br>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<br>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 |
| C12135 | P12135 | CN12135 | Vedolizumab | Moderate to severe ulcerative colitis<br>Continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or | Compliance with Authority Required procedures |

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| | | | | 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 vedolizumab subcutaneous form continuing restriction; AND<br>Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.<br>Up to a maximum of 2 repeats will be authorised.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C12137 | P12137 | CN12137 | Vedolizumab | Severe Crohn disease<br>Continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];<br>Patient must be aged 18 years or older;<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or<br>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 vedolizumab subcutaneous form continuing restriction; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment; AND<br>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease. or<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(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.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following | Compliance with Written Authority Required procedures |

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| | | | | (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or<br>(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and<br>(iii) the date of clinical assessment.<br>All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.<br>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.<br>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | continuing authority applications, or for treatment that would otherwise extend the continuing treatment period. | |
| C12138 | P12138 | CN12138 | Obeticholic acid | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)<br>Continuing treatment<br>Must be treated by a prescriber who is either:<br>(i) a gastroenterologist, (ii) a hepatologist; or<br>Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND<br>Patient must be undergoing continuing PBS-subsidised treatment with this drug, with treatment having commenced through one of:<br>(i) the 'Initial treatment' listing, (ii) 'Grandfather' arrangements; AND<br>Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; or<br>Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated; AND<br>Patient must have achieved an adequate response to this drug, defined as having at least one of:<br>(i) an alkaline phosphate (ALP) level less than 1.67 times the upper limit of normal (ULN), (ii) a reduction in the ALP reading of at least 15% compared to the baseline level provided with the initial authority application, (iii) a total bilirubin level within the normal reference range.<br>The improvement in the qualifying laboratory reading(s) has/have been documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12138 |
| C12140 | P12140 | CN12140 | Obeticholic acid | Primary biliary cholangitis (previously known as Primary biliary cirrhosis)<br>Transitioning from non-PBS to PBS subsidised supply - Grandfather arrangements<br>Must be treated by a prescriber who is either:<br>(i) a gastroenterologist, (ii) a hepatologist; or<br>Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND | Compliance with Authority Required procedures |

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| | | | | Patient must be undergoing concurrent treatment with ursodeoxycholic acid, following this authority application; or<br>Patient must be undergoing treatment with this drug as monotherapy following this authority application, because combination treatment with ursodeoxycholic acid is not tolerated; AND<br>Patient must have received treatment with this drug for this PBS indication prior to 1 September 2021; AND<br>Patient must have experienced an inadequate response to ursodeoxycholic acid, despite treatment with ursodeoxycholic acid for at least 52 weeks at a therapeutic dose, prior to initiating treatment with this drug; or<br>Patient must have experienced an intolerance to ursodeoxycholic acid of a severity requiring permanent treatment discontinuation, prior to initiating treatment with this drug; AND<br>Patient must not have/be each of:<br>(i) severe liver disease, (ii) immunocompromised; AND<br>Patient must have had, prior to initiating treatment with this drug, an alkaline phosphatase (ALP) level of at least 1.67 times the upper limit of normal (ULN) having accounted for each of:<br>(i) age, (ii) gender, (iii) laboratory to laboratory variances in the definition of 'normal', despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; or<br>Patient must have had, prior to initiating treatment with this drug, a total bilirubin level between 1 to 2 times the ULN, despite treatment with ursodeoxycholic acid for at least 52 cumulative weeks; or<br>Patient must have had, prior to initiating treatment with this drug, abnormal readings of at least one of:<br>(i) alkaline phosphatase (ii) total bilirubin, in the presence of an intolerance of a severity requiring treatment discontinuation with ursodeoxycholic acid;<br>Patient must be aged 18 years or older.<br>Document and retain in the patient's medical records the qualifying baseline laboratory reading for the purpose of assessing response to treatment under the 'Continuing treatment' restriction. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C12147 | P12147 | CN12147 | Adalimumab | Complex refractory Fistulising Crohn disease<br>Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>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<br>Patient must have an externally draining enterocutaneous or rectovaginal fistula.<br>Applications for authorisation must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes 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.<br>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
| C12148 | P12148 | CN12148 | Adalimumab | Complex refractory Fistulising Crohn disease<br>Subsequent continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or | Compliance with Written Authority Required procedures |

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| | | | | Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug for this condition.<br>An adequate response is defined as<br>(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or<br>(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.<br>Applications for authorisation must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.<br>The most recent fistula assessment must be no more than 4 weeks old at the time of application.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised. | |

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| | | | | 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.<br>A maximum of 24 weeks treatment will be authorised under this restriction. | |
| C12152 | P12152 | CN12152 | Adalimumab | Complex refractory Fistulising Crohn disease<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>Applications for authorisation must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following<br>(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and | Compliance with Written Authority Required procedures |

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| | | | | (ii) details of prior biological medicine treatment including details of date and duration of treatment.<br>The most recent fistula assessment must be no more than 4 weeks old at the time of application.<br>A maximum of 16 weeks of treatment with this drug will be approved under this criterion. | |
| C12155 | P12155 | CN12155 | Adalimumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the | Compliance with Written Authority Required procedures |

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| | | | | most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following<br>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12156 | P12156 | CN12156 | Adalimumab | Severe chronic plaque psoriasis<br>Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply<br>Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; or<br>Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; or<br>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 | Compliance with Authority Required procedures |

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| | | | | 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<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Must be treated by a dermatologist. | |
| C12157 | P12157 | CN12157 | Adalimumab | Severe chronic plaque psoriasis<br>Subsequent continuing treatment, Whole body<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. | Compliance with Written Authority Required procedures |

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| | | | | An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12158 | P12158 | CN12158 | Adalimumab | Severe chronic plaque psoriasis<br>First continuing treatment, Whole body<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as<br>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and | Compliance with Written Authority Required procedures |

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| | | | | (2) a 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.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12163 | P12163 | CN12163 | Tocilizumab | Severe active juvenile idiopathic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND<br>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of | Compliance with Written Authority Required procedures |

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

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.<br>The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.<br>If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.<br>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include<br>(1) completed authority prescription form(s); and<br>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.<br>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority | |

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| | | | | prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C12164 | P12164 | CN12164 | Etanercept | Severe active juvenile idiopathic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND<br>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:<br>(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<br>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 | Compliance with Written Authority Required procedures |

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

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include<br>(1) completed authority prescription form(s); and<br>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C12174 | P12174 | CN12174 | Adalimumab<br>Tofacitinib<br>Upadacitinib | Ankylosing spondylitis<br>Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND<br>Must be treated by a rheumatologist. or<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
| C12178 | P12178 | CN12178 | Vedolizumab | Severe Crohn disease<br>Continuing treatment with subcutaneous form or switching from intravenous form to subcutaneous form<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; or<br>Patient must have received this drug in the intravenous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab intravenous form continuing treatment restriction; AND | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or<br>Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:<br>(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; or<br>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or<br>(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and<br>(iii) the date of clinical assessment.<br>An application for the continuing treatment must be accompanied with the assessment of response 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 | |

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| | | | | will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction.<br>Up to a maximum of 5 repeats will be authorised.<br>If fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone or electronically via the Online PBS Authorities system and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will immediate assessment approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period. | |
| C12179 | P12179 | CN12179 | Vedolizumab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Application for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.<br>At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.<br>Up to a maximum of 2 repeats will be authorised.<br>Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted | |

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| | | | | following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. 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. | |
| C12189 | P12189 | CN12189 | Adalimumab | Severe chronic plaque psoriasis<br>First continuing treatment, Face, hand, foot<br>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older; | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes 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.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.<br>The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. | |

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| | | | | A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12190 | P12190 | CN12190 | Adalimumab | Severe chronic plaque psoriasis<br>Subsequent continuing treatment, Face, hand, foot<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes 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.<br>The most recent PASI assessment must be no more than 4 weeks old at the time of application.<br>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12193 | P12193 | CN12193 | Tocilizumab | Severe active juvenile idiopathic arthritis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND<br>Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:<br>(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 | Compliance with Written Authority Required procedures |

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| | | | | 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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application<br>an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either<br>(a) an active joint count of at least 20 active (swollen and tender) joints; or<br>(b) at least 4 active joints from the following list<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(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).<br>The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.<br>If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.<br>The authority application must be made in writing and must include<br>(1) completed authority prescription form(s); and<br>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C12194 | P12194 | CN12194 | Adalimumab | Severe active juvenile idiopathic arthritis<br>Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>An adequate response to treatment is defined as<br>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or<br>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or<br>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder, 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).<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.<br>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. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C12212 | P12212 | CN12212 | Adalimumab | Severe chronic plaque psoriasis<br>Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND<br>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must be as systemic monotherapy (other than methotrexate); AND<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older;<br>Must be treated by a dermatologist.<br>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing<br>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or<br>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.<br>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form(s); and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following<br>(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<br>(ii) details of prior biological treatment, including dosage, date and duration of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12214 | P12214 | CN12214 | Adalimumab | Severe active juvenile idiopathic arthritis<br>Subsequent continuing treatment<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;<br>Patient must be aged 18 years or older. | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | An adequate response to treatment is defined as<br>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or<br>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or<br>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder, 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).<br>Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.<br>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.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request 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.<br>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. | |
| C12219 | P12219 | CN12219 | Vedolizumab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND<br>Patient must have a Mayo clinic score greater than or equal to 6; or | Compliance with Written Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Application for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and<br>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.<br>A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>Details of the accepted toxicities including severity can be found on the Services Australia website. | |
| C12220 | P12220 | CN12220 | Vedolizumab | Severe Crohn disease<br>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND<br>Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND<br>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following<br>(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or<br>(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and<br>(iii) the date of clinical assessment; and<br>(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.<br>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.<br>Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.<br>If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.<br>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.<br>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12221 | P12221 | CN12221 | Vedolizumab | Severe Crohn disease<br>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND<br>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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<br>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<br>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<br>Patient must have evidence of intestinal inflammation; or<br>Patient must be assessed clinically as being in a high faecal output state; or<br>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<br>The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction; AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Applications for authorisation must be made in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following<br>(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and<br>(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and<br>(iii) the date of the most recent clinical assessment.<br>Evidence of intestinal inflammation includes | |

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| | | | | (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<br>(ii) faeces higher than normal lactoferrin or calprotectin level; or<br>(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.<br>A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.<br>If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.<br>Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | |
| C12225 | P12225 | CN12225 | Lacosamide | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures<br>Dose titration at the start of therapy, during therapy or to gradually cease treatment<br>Must be treated by a neurologist; or<br>Must be treated by a paediatrician; AND<br>The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced; AND<br>The treatment must be (for initiating treatment)/have been (for continuing treatment) in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug is/was first commenced; AND<br>The treatment must be for dose titration purposes. | Compliance with Authority Required procedures - Streamlined Authority Code 12225 |
| C12228 | P12228 | CN12228 | Adalimumab | Complex refractory Fistulising Crohn disease<br>First continuing treatment<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated an adequate response to treatment with this drug for this condition.<br>An adequate response is defined as<br>(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or<br>(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.<br>Applications for authorisation must be made in writing and must include<br>(1) a completed authority prescription form; and | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (2) a 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.<br>The most recent fistula assessment must be no more than 4 weeks old at the time of application.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.<br>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.<br>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.<br>A maximum of 24 weeks treatment will be authorised under this restriction. | |
| C12229 | P12229 | CN12229 | Adalimumab | Complex refractory Fistulising Crohn disease<br>Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>Patient must have an externally draining enterocutaneous or rectovaginal fistula.<br>Applications for authorisation must be made in writing and must include<br>(1) two completed authority prescription forms; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes 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.<br>A maximum of 16 weeks of treatment with this drug will be approved under this criterion.<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | |
| C12240 | P12240 | CN12240 | Adalimumab | Complex refractory Fistulising Crohn disease<br>Continuing treatment - balance of supply<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing treatment restriction to complete 24 weeks treatment; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | |
| C12242 | P12242 | CN12242 | Vedolizumab | Moderate to severe ulcerative colitis<br>Initial treatment with subcutaneous form<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); or<br>Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); or<br>Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); or<br>Patient must have a concurrent authority application for the intravenous infusion for this condition under either 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); AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.<br>Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16. | Compliance with Written Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C12261 | P12261 | CN12261 | Etanercept | Severe chronic plaque psoriasis<br>Balance of supply - Initial 1, 2, 3 or 4 treatment (Whole body, or, face/hand/foot)<br>Must be treated by a dermatologist; AND<br>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):<br>(i) Initial 1, (ii) Initial 2, (iii) Initial 3, (iv) Initial 4; AND<br>The treatment must be as systemic monotherapy; or<br>The treatment must be in combination with methotrexate; AND<br>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<br>Continuing treatment | Compliance with Authority Required procedures - |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have previously been issued with an authority prescription for this drug; AND<br>The treatment must not exceed a lifetime maximum of 18 months therapy; AND<br>Must be treated by a specialist. or<br>Must be treated by a consultant physician. | Streamlined Authority Code 12270 |
| C12271 | P12271 | CN12271 | Durvalumab | Unresectable Stage III non-small cell lung cancer<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND<br>The treatment must not exceed 12 months in total for this condition under the initial and continuing restriction combined; AND<br>The treatment must be once in a lifetime with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12271 |
| C12272 | P12272 | CN12272 | Adalimumab | Moderate to severe hidradenitis suppurativa<br>Subsequent continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND<br>Patient must have demonstrated a response to treatment with this drug for this condition; AND<br>Must be treated by a dermatologist.<br>A response to treatment is defined as<br>Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result. | |
| C12273 | P12273 | CN12273 | Adalimumab | Moderate to severe hidradenitis suppurativa<br>Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or<br>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (recommencement of treatment) restriction to complete 16 weeks treatment; AND<br>Must be treated by a dermatologist.<br>A maximum of 12 weeks of treatment will be authorised under this restriction. | Compliance with Authority Required procedures |
| C12275 | P12275 | CN12275 | Adalimumab | Moderate to severe hidradenitis suppurativa<br>Initial treatment - Initial 2 (recommencement of treatment)<br>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<br>Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be limited to a maximum duration of 16 weeks; AND<br>Must be treated by a dermatologist.<br>Assessment of disease severity must be no more than 4 weeks old at the time of application. | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | A response to treatment is defined as<br>Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes<br>(i) the Hurley stage grading; and<br>(ii) the AN count. | |
| C12278 | P12278 | CN12278 | Adalimumab | Moderate to severe hidradenitis suppurativa<br>Initial treatment - Initial 1 (new patient)<br>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<br>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<br>Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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<br>The treatment must be limited to a maximum duration of 16 weeks; AND<br>Must be treated by a dermatologist.<br>Assessment of disease severity must be no more than 4 weeks old at the time of application.<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes<br>(i) the Hurley stage grading; and<br>(ii) the AN count; and<br>(iii) the name of the antibiotic/s received for two separate courses each of three months; or<br>(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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12285 | P12285 | CN12285 | Ustekinumab | Severe chronic plaque psoriasis<br>Balance of supply - Continuing treatment (Whole body, or, face/hand/foot)<br>Must be treated by a dermatologist; AND<br>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 |
| C12306 | P12306 | CN12306 | Adalimumab | Moderate to severe hidradenitis suppurativa<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated a response to treatment with this drug for this condition; AND<br>Must be treated by a dermatologist.<br>A response to treatment is defined as<br>Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and | Compliance with Authority Required procedures |

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| | | | | (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result. | |
| C12313 | P12313 | CN12313 | Infliximab | Moderate to severe ulcerative colitis<br>Initial treatment - Initial 1 (new patient)<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or<br>Must be treated by a paediatrician; or<br>Must be treated by a specialist paediatric gastroenterologist; AND<br>Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND<br>Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or<br>Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or<br>Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (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<br>Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; or<br>Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); or | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years;<br>Patient must be 6 years of age or older.<br>Application for authorisation must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes the following<br>(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<br>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].<br>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.<br>All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.<br>The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.<br>An adult patient who has previously received induction therapy with PBS-subsidised treatment 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 scoreless than or equal to 2, with no subscore greater than 1, will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.<br>A patient, aged 6 to 17 years, who has previously received induction therapy with PBS-subsidised treatment 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 PUCAI score of less than 10 will not be | |

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| | | | | required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.<br>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.<br>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>Details of the accepted toxicities including severity can be found on the Services Australia website. | |
| C12315 | P12315 | CN12315 | Adalimumab | Moderate to severe hidradenitis suppurativa<br>First continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated a response to treatment with this drug for this condition; AND<br>Must be treated by a dermatologist.<br>A response to treatment is defined as | Compliance with Authority Required procedures |

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| | | | | Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.<br>An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result. | |
| C12334 | P12334 | CN12334 | Ustekinumab | Severe chronic plaque psoriasis<br>Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)<br>Must be treated by a dermatologist; AND<br>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):<br>(i) Initial 1, (ii) Initial 2, (iii) Initial 3; AND<br>The treatment must be as systemic monotherapy; or<br>The treatment must be in combination with methotrexate; AND<br>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 |

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| C12336 | P12336 | CN12336 | Adalimumab | Moderate to severe hidradenitis suppurativa<br>Initial treatment - Initial 1 (new patient)<br>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<br>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<br>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<br>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<br>The treatment must be limited to a maximum duration of 16 weeks; AND<br>Must be treated by a dermatologist.<br>Assessment of disease severity must be no more than 4 weeks old at the time of application.<br>An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>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<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and | Compliance with Authority Required procedures |

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| | | | | (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes<br>(i) the Hurley stage grading; and<br>(ii) the AN count; and<br>(iii) the name of the antibiotic/s received for two separate courses each of three months; or<br>(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. | |
| C12349 | P12349 | CN12349 | Beclometasone with formoterol and glycopyrronium<br>Budesonide with glycopyrronium and formoterol<br>Fluticasone furoate with umeclidinium and vilanterol | Chronic obstructive pulmonary disease (COPD)<br>Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; or<br>Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition; AND<br>Patient must not be undergoing treatment with this product in each of the following circumstances:<br>(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<br>Triptorelin | Central precocious puberty<br>Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy<br>Must be treated by a medical practitioner identifying as one of:<br>(i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; or | |

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| | | | | 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<br>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<br>Initial treatment<br>Must be treated by a paediatric endocrinologist; or<br>Must be treated by an endocrinologist specialising in paediatrics;<br>Patient must be of an age that is prior to their 12th birthday if female; or<br>Patient must be of an age that is prior to their 13th birthday if male;<br>Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9th birthday if female. or<br>Patient must have had onset of signs/symptoms of central precocious puberty prior to their 10th birthday if male. | |
| C12392 | P12392 | CN12392 | Certolizumab pegol<br>Secukinumab | Non-radiographic axial spondyloarthritis<br>Continuing treatment - balance of supply<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment; AND<br>Must be treated by a rheumatologist. or<br>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. | Compliance with Authority Required procedures |
| C12399 | P12399 | CN12399 | Tocilizumab | Severe active juvenile idiopathic arthritis<br>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND | Compliance with Authority Required procedures |

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| | | | | Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>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.<br>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.<br>An adequate response to treatment is defined as<br>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or<br>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or<br>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to | |

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| | | | | active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.<br>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. | |
| C12404 | P12404 | CN12404 | Tocilizumab | Severe active juvenile idiopathic arthritis<br>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)<br>Must be treated by a paediatric rheumatologist; or<br>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND<br>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;<br>Patient must be under 18 years of age.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>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.<br>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.<br>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.<br>An adequate response to treatment is defined as<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder, 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).<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of | |

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| | | | | therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. 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.<br>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. | |
| C12405 | P12405 | CN12405 | Tocilizumab | Severe active rheumatoid arthritis<br>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND<br>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 | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>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.<br>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.<br>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.<br>An adequate response to treatment is defined as<br>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>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 | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | |
| C12425 | P12425 | CN12425 | Bosentan | Pulmonary arterial hypertension (PAH)<br>Cessation of treatment (all patients)<br>Patient must be receiving PBS-subsidised treatment with this PAH agent; AND<br>The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy; AND<br>Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.<br>The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved. | Compliance with Authority Required procedures |
| C12435 | P12435 | CN12435 | Lanadelumab | Chronic treatment of hereditary angioedema Types 1 or 2<br>Continuing preventative treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not be PBS-subsidised in combination with a C1-esterase inhibitor concentrate; AND<br>Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist;<br>Patient must be aged 12 years or older. | Compliance with Authority Required procedures |

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| | | | | Patients who have successfully transitioned to a lower dosing frequency should be reviewed every 6 months to ensure they continue to demonstrate a sustained response<br>For the purposes of administering this restriction, an adequate response is a reduction of the baseline number of acute attacks of hereditary angioedema of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate. The details of the reduction must be documented in the patient's medical records for auditing purposes. | |
| C12436 | P12436 | CN12436 | Tocilizumab | Severe active juvenile idiopathic arthritis<br>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)<br>Must be treated by a paediatric rheumatologist; or<br>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND<br>Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be under 18 years of age.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>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.<br>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 | Compliance with Authority Required procedures |

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| | | | | patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>An adequate response to treatment is defined as<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or<br>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder, 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).<br>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient 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 | |

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| | | | | 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.<br>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. | |
| C12439 | P12439 | CN12439 | Azacitidine | Acute Myeloid Leukaemia<br>The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses). | Compliance with Authority Required procedures |
| C12440 | P12440 | CN12440 | Ripretinib | Metastatic or unresectable malignant gastrointestinal stromal tumour<br>Initial treatment<br>The condition must not be resectable; AND<br>The treatment must be as monotherapy; AND<br>The condition must have progressed despite treatment with all drugs PBS-listed specifically for this PBS-indication; or<br>The condition must have progressed despite each of:<br>(i) treatment with a drug PBS-listed specifically listed for this PBS-indication, (ii) an intolerance/expected intolerance to all other drugs PBS-listed for this specific PBS-indication; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>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 |
| C12450 | P12450 | CN12450 | Tocilizumab | Severe active juvenile idiopathic arthritis<br>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilzumab after resolution of the critical shortage of tocilizumab)<br>Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND | Compliance with Authority Required procedures |

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| | | | | Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>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.<br>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.<br>An adequate response to treatment is defined as<br>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or<br>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or<br>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to | |

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| | | | | active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.<br>A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.<br>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. | |
| C12451 | P12451 | CN12451 | Tocilizumab | Severe active rheumatoid arthritis<br>Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab) | Compliance with Authority Required procedures |

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| | | | | Must be treated by a rheumatologist; or<br>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND<br>Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND<br>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<br>Patient must not receive more than 16 weeks of treatment under this restriction;<br>Patient must be aged 18 years or older.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>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.<br>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.<br>A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.<br>An adequate response to treatment is defined as<br>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;<br>AND either of the following<br>(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or | |

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| | | | | (b) a reduction in the number of the following active joints, from at least 4, by at least 50%<br>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or<br>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).<br>At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.<br>To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | |
| C12455 | P12455 | CN12455 | Ripretinib | Metastatic or unresectable malignant gastrointestinal stromal tumour<br>Continuing treatment<br>The condition must not be resectable; AND<br>Patient must have received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be as monotherapy; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures |

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| C12459 | P12459 | CN12459 | High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate | Ketogenic diet<br>Patient must have intractable seizures requiring treatment with a ketogenic diet; or<br>Patient must have a glucose transport protein defect; or<br>Patient must have pyruvate dehydrogenase deficiency; AND<br>Patient must have severe intestinal malabsorption of whole protein ketogenic diet formula; AND<br>Patient must have unsuccessfully trialled at least one of the PBS-listed products with the indication of:<br>'Ketogenic diet'.<br>This product must only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. | Compliance with Authority Required procedures |
| C12462 | P12462 | CN12462 | Venetoclax | Acute Myeloid Leukaemia<br>The condition must be previously untreated at the time of initiation with this drug (except for essential treatment with hydroxyurea or leukapheresis); AND<br>Patient must not be considered eligible for standard intensive remission induction chemotherapy at the time of initiation with this drug; AND<br>The treatment must be used in combination with azacitidine (refer to Product Information for timing of azacitidine and venetoclax doses); AND<br>Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The condition must not be acute promyelocytic leukaemia.<br>Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.<br>If abnormal blood counts suggest the potential for relapsed AML, 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<br>Initial 1: New patient (commencing with no previous treatment with C1-INH for routine prophylaxis)<br>Patient must have experienced at least 12 treated acute attacks of hereditary angioedema within the 6 month period prior to commencing treatment with this drug; AND | Compliance with Authority Required procedures |

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| | | | | Patient must not have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema at the time of application; AND<br>The treatment must not be used in combination with a C1-esterase inhibitor concentrate; AND<br>Must be treated by a clinical immunologist or a specialist allergist;<br>Patient must be aged 12 years or older.<br>For the purposes of administering this restriction, acute attacks of hereditary angioedema are those of a severity necessitating immediate medical intervention with either (i) icatibant, or (ii) C1-esterase inhibitor concentrate<br>The baseline measurement of the number of treated acute attacks of hereditary angioedema within the 6 months prior to initiating treatment must be provided at the time of submitting this application. | |
| C12467 | P12467 | CN12467 | Lanadelumab | Chronic treatment of hereditary angioedema Types 1 or 2<br>Initial 2: New patient (commencing from National Blood Authority-funded C1-INH)<br>Patient must have been receiving a C1-esterase inhibitor through the National Blood Authority as routine prophylaxis for hereditary angioedema immediately prior to receiving lanadelumab; AND<br>The treatment must not be used in combination with a C1-esterase inhibitor concentrate; AND<br>Must be treated by a clinical immunologist or a specialist allergist;<br>Patient must be aged 12 years or older. | Compliance with Authority Required procedures |
| C12470 | P12470 | CN12470 | Cetuximab | Metastatic colorectal cancer<br>Continuing treatment<br>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<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 12480 |

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| | | | | Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | |
| C12483 | P12483 | CN12483 | Cetuximab | Metastatic colorectal cancer<br>Initial treatment<br>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<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with cetuximab; AND<br>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12484 |
| C12487 | P12487 | CN12487 | Encorafenib | Metastatic colorectal cancer<br>Initial treatment<br>Patient must have BRAF V600 variant positive metastatic colorectal cancer; AND<br>The treatment must be in combination with cetuximab; AND<br>Patient must not have received prior treatment with cetuximab for this condition; or<br>Patient must not have developed disease progression while receiving cetuximab for this condition; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The condition must have failed to respond to at least one other line of systemic therapy; AND<br>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<br>Initial treatment<br>The condition must be refractory to a prior therapy with rituximab within 6 months after completion of treatment with rituximab; AND | Compliance with Authority Required procedures |

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| | | | | The condition must be refractory to a prior therapy with an alkylating agent within 6 months after completion of treatment with an alkylating agent; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.<br>The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.<br>The date of completion of prior therapies with rituximab and an alkylating agent must be documented in the patient's medical records. | |
| C12491 | P12491 | CN12491 | Idelalisib | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for Chronic lymphocytic leukaemia; or<br>Patient must have previously received PBS-subsidised treatment with this drug for Small lymphocytic leukaemia; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C12492 | P12492 | CN12492 | Teriparatide | Severe established osteoporosis<br>Initial treatment<br>Must be treated by a specialist; or<br>Must be treated by a consultant physician; AND<br>Patient must be at very high risk of fracture; AND<br>Patient must have a bone mineral density (BMD) T-score of -3.0 or less; AND<br>Patient must have had 2 or more fractures due to minimal trauma; AND<br>Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not exceed a lifetime maximum of 18 months therapy; AND<br>Patient must not have received treatment with PBS-subsidised romosozumab. or | Compliance with Authority Required procedures - Streamlined Authority Code 12492 |

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| | | | | Patient must have developed intolerance to romosozumab of a severity necessitating permanent treatment withdrawal within the first 6 months of therapy.<br>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.<br>If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.<br>If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.<br>Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months and zoledronic acid 5 mg per annum.<br>Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be documented in the patient's medical record. | |
| C12493 | P12493 | CN12493 | Upadacitinib | Chronic severe atopic dermatitis<br>Continuing or resuming treatment with this drug of the whole body<br>Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the whole body; AND<br>Patient must have achieved an adequate response prior to this first continuing treatment authority application; or<br>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 | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>Must be treated by a dermatologist; or<br>Must be treated by a clinical immunologist; AND<br>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:<br>chronic severe atopic dermatitis).<br>For the purposes of this restriction, an adequate response to treatment is defined as<br>(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and<br>(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline<br>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.<br>State each of the current EASI and DLQI scores for this authority application. | |
| C12494 | P12494 | CN12494 | Upadacitinib | Chronic severe atopic dermatitis<br>Continuing or resuming treatment with this drug of the face and/or hands<br>Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the face/hands; AND<br>Patient must have achieved an adequate response prior to this first continuing treatment authority application; or<br>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<br>Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application; AND<br>Must be treated by a dermatologist; or<br>Must be treated by a clinical immunologist; AND<br>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:<br>chronic severe atopic dermatitis).<br>For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as<br>(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<br>(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and<br>(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline<br>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.<br>Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes | |
| C12495 | P12495 | CN12495 | Acalabrutinib<br>Ibrutinib<br>Zanubrutinib | Mantle cell lymphoma<br>Initial treatment<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must be untreated with Bruton's tyrosine kinase inhibitor therapy. or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12497 | P12497 | CN12497 | Dupilumab | Chronic severe atopic dermatitis<br>Initial treatment of the whole body<br>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<br>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<br>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<br>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:<br>(i) the whole body, (ii) face/hands; AND<br>The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND<br>Patient must not have experienced an inadequate response to this biological medicine in this PBS indication; AND<br>Must be treated by a dermatologist; or<br>Must be treated by a clinical immunologist;<br>Patient must be 12 years of age or older.<br>State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.<br>Acceptable scores can be<br>(a) current scores; or<br>(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records. | |
| C12499 | P12499 | CN12499 | Upadacitinib | Chronic severe atopic dermatitis<br>Initial treatment with this drug of the whole body<br>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<br>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<br>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<br>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:<br>(i) the whole body, (ii) face/hands; AND<br>Patient must not have experienced an inadequate response to this therapy; AND<br>Must be treated by a dermatologist; or<br>Must be treated by a clinical immunologist; AND<br>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:<br>chronic severe atopic dermatitis);<br>Patient must be 12 years of age or older.<br>State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.<br>Acceptable scores can be | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (a) current scores; or<br>(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.<br>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.<br>Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records. | |
| C12500 | P12500 | CN12500 | Acalabrutinib<br>Ibrutinib<br>Zanubrutinib | Mantle cell lymphoma<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition. | Compliance with Authority Required procedures |
| C12504 | P12504 | CN12504 | Upadacitinib | Chronic severe atopic dermatitis<br>Dose change (increasing up to the 30 mg dose, or, decreasing back down to the 15 mg dose) - whole body, or, face/hands<br>Patient must not be undergoing each of:<br>(i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase on more than 2 consecutive occasions; AND<br>Patient must be undergoing existing PBS-subsidised treatment with this therapy where each of the following is true:<br>(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<br>Must be treated by a dermatologist; or<br>Must be treated by a clinical immunologist; AND<br>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:<br>chronic severe atopic dermatitis). | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C12507 | P12507 | CN12507 | Dupilumab | Chronic severe atopic dermatitis<br>Initial treatment of the face and/or hands<br>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<br>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<br>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<br>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:<br>(i) the whole body, (ii) face/hands; AND<br>The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND<br>Patient must not have experienced an inadequate response to this biological medicine in this PBS indication; AND<br>Must be treated by a dermatologist; or<br>Must be treated by a clinical immunologist;<br>Patient must be 12 years of age or older.<br>State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for<br>(i) erythema,<br>(ii) oedema/papulation,<br>(iii) excoriation,<br>(iv) lichenification<br>(a) current scores; or<br>(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Acceptable scores can be<br>(a) current scores; or<br>(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.<br>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.<br>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.<br>Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records. | |
| C12508 | P12508 | CN12508 | Upadacitinib | Chronic severe atopic dermatitis<br>Initial treatment with this drug of the face and/or hands<br>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<br>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<br>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<br>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:<br>(i) the whole body, (ii) face/hands; AND<br>Patient must not have experienced an inadequate response to this therapy; AND<br>Must be treated by a dermatologist; or<br>Must be treated by a clinical immunologist; AND | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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:<br>chronic severe atopic dermatitis);<br>Patient must be 12 years of age or older.<br>State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for<br>(i) erythema,<br>(ii) oedema/papulation,<br>(iii) excoriation,<br>(iv) lichenification<br>(a) current scores; or<br>(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.<br>Acceptable scores can be<br>(a) current scores; or<br>(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.<br>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.<br>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.<br>Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records. | |
| C12522 | P12522 | CN12522 | Dasatinib<br>Nilotinib | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - third-line therapy<br>Patient must have received initial PBS-subsidised treatment with this drug as a third-line therapy for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 12522 |

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| | | | | Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | |
| C12524 | P12524 | CN12524 | Dasatinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - second-line therapy<br>The condition must be in the chronic phase; or<br>The condition must be in the accelerated phase; or<br>The condition must be in the blast phase; AND<br>Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; AND<br>Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; or<br>Patient must have failed an adequate trial of PBS-subsidised first-line treatment with nilotinib for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Failure of an adequate trial of imatinib or nilotinib is defined as<br>(i) Lack of response to initial imatinib or nilotinib therapy, defined as either<br>(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR<br>(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 | Compliance with Authority Required procedures |

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| | | | | fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR<br>(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>(2) Extramedullary involvement other than spleen and liver; OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>- 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<br>- 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<br>- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR<br>(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (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<br>(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>(2) Extramedullary involvement other than spleen and liver; OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>Accelerated phase is defined by the presence of 1 or more of the following<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or | |

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| | | | | (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome);<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>(2) Extramedullary involvement other than spleen and liver; OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>Blast crisis is defined as either<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>(2) Extramedullary involvement other than spleen and liver; OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>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.<br>A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.<br>Pathology report(s) confirming a loss of response to imatinib or 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. | |
| C12525 | P12525 | CN12525 | Imatinib | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment<br>Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; AND | Compliance with Authority Required procedures - |

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| | | | | The condition must be in the blast phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis. or<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR). | Streamlined Authority Code 12525 |
| C12527 | P12527 | CN12527 | Imatinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy<br>The condition must be a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the accelerated phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Accelerated phase is defined by the presence of 1 or more of the following<br>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>3. Peripheral basophils greater than or equal to 20%; or<br>4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records. | Compliance with Authority Required procedures |

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| | | | | 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. | |
| C12529 | P12529 | CN12529 | Nilotinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - second-line therapy<br>The condition must be in the chronic phase; or<br>The condition must be in the accelerated phase; AND<br>Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; AND<br>Patient must have failed an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; or<br>Patient must have failed an adequate trial of PBS-subsidised first-line treatment with dasatinib for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Failure of an adequate trial of imatinib or dasatinib is defined as<br>(i) Lack of response to initial imatinib or dasatinib therapy, defined as either<br>(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR<br>(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR<br>(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia. | Compliance with Authority Required procedures |

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

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| | | | | (3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR<br>(v) Disease progression (defined as a greater than or equal to.<br>Accelerated phase is defined by the presence of 1 or more of the following<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR<br>(v) Disease progression (defined as a greater than or equal to.<br>50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.<br>Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.<br>A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12530 | P12530 | CN12530 | Dasatinib | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - second-line therapy<br>Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with nilotinib for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12530 |
| C12531 | P12531 | CN12531 | Methoxsalen | Chronic graft versus host disease<br>Continuing treatment<br>Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both:<br>(i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment; AND<br>Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode; AND<br>Must be treated by a haematologist; or<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or | Compliance with Authority Required procedures - Streamlined Authority Code 12531 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition; AND<br>Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse. | |
| C12536 | P12536 | CN12536 | Imatinib | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - first-line therapy<br>The condition must be in the chronic phase; AND<br>Patient must have received initial continuing PBS-subsidised treatment with this drug as a first-line therapy for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12536 |
| C12541 | P12541 | CN12541 | Imatinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy<br>The condition must be a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the chronic phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.<br>Patients should be commenced on a dose of imatinib mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.<br>The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records. | |
| C12542 | P12542 | CN12542 | Imatinib | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment<br>Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; AND<br>The condition must be in the accelerated phase; AND | Compliance with Authority Required procedures - Streamlined Authority Code 12542 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis. or<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR). | |
| C12543 | P12543 | CN12543 | Imatinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy<br>The condition must be a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the blast phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Blast crisis is defined as either<br>1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>2. Extramedullary involvement other than spleen and liver.<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.<br>The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C12546 | P12546 | CN12546 | Methoxsalen | Chronic graft versus host disease<br>Initial treatment in a treatment episode<br>The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; or | Compliance with Authority Required procedures - |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; or<br>The condition must have relapsed with each of the following conditions being met:<br>(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<br>Patient must be undergoing treatment with this drug that is being administered within at least one of:<br>(i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25$^{th}$ dose) of a treatment episode; AND<br>Must be treated by a haematologist; or<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation; AND<br>Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition. | Streamlined Authority Code 12546 |
| C12549 | P12549 | CN12549 | Nilotinib | Chronic Myeloid Leukaemia (CML)<br>Grandfather treatment for patients initiated with nilotinib 200 mg prior to 1 April 2012 as first-line therapy<br>The condition must be in the chronic phase; AND<br>Patient must have received PBS-subsidised treatment with nilotinib 200mg as a first-line therapy for this condition prior to 1 April 2012; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12549 |

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| | | | | 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. | |
| C12557 | P12557 | CN12557 | Nilotinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy<br>Patient must have a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the chronic phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.<br>Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records. | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12559 | P12559 | CN12559 | Gemtuzumab ozogamicin | Acute Myeloid Leukaemia<br>Induction treatment<br>Patient must have confirmed CD33-positive AML prior to initiation of treatment; AND<br>The condition must be de novo; AND<br>The condition must be previously untreated at the time of initiation (except for prior essential treatment with hydroxyurea or leukapheresis for patients with hyperleukocytic AML); AND<br>Patient must have confirmed intermediate/favourable cytogenetic risk; or<br>Patient must have unknown cytogenetic risk due to inconclusive test results; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND<br>The condition must not be acute promyelocytic leukaemia; AND<br>The treatment must be in combination with standard intensive remission induction chemotherapy for this condition, which must include cytarabine and an anthracycline; AND<br>The treatment must not be used in combination with a tyrosine kinase inhibitor; AND<br>The condition must not be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive; AND<br>Patient must not receive more than 1 induction cycle under this restriction in a lifetime.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting. | Compliance with Authority Required procedures |
| C12561 | P12561 | CN12561 | Dasatinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - third-line therapy<br>The condition must be in the chronic phase; or | Compliance with Authority Required procedures |

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| | | | | The condition must be in the accelerated phase; or<br>The condition must be in the blast phase; AND<br>Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; or<br>Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting; AND<br>Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; AND<br>Patient must have failed an adequate trial of PBS-subsidised second-line treatment with nilotinib for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Failure of an adequate trial of nilotinib is defined as<br>(i) Lack of response to second line nilotinib therapy, defined as either<br>(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing nilotinib therapy; OR<br>(iv) Development of accelerated phase or blast crisis in a patient previously prescribed nilotinib for any phase of chronic myeloid leukaemia.<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>(2) Extramedullary involvement other than spleen and liver; OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>- failure to achieve a haematological response after a minimum of 3 months therapy with nilotinib for patients initially treated in chronic phase; or<br>- 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<br>- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with nilotinib; OR<br>ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing nilotinib therapy; OR<br>(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing nilotinib therapy; OR<br>(iv) Development of accelerated phase or blast crisis in a patient previously prescribed nilotinib for any phase of chronic myeloid leukaemia.<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or | |

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| | | | | (5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>(2) Extramedullary involvement other than spleen and liver; OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>Accelerated phase is defined by the presence of 1 or more of the following<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>(2) Extramedullary involvement other than spleen and liver; OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>Blast crisis is defined as either<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or<br>(2) Extramedullary involvement other than spleen and liver; OR<br>(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during nilotinib | |

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| | | | | therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.<br>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.<br>A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.<br>Pathology report(s) confirming a loss of response to imatinib and 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. | |
| C12563 | P12563 | CN12563 | Nilotinib | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - second-line therapy<br>Patient must have received initial PBS-subsidised treatment with this drug as a second-line therapy for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second-line treatment with dasatinib for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 12563 |
| C12565 | P12565 | CN12565 | Dasatinib | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - first-line therapy<br>The condition must be in the chronic phase; AND | Compliance with Authority Required procedures - |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with nilotinib for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records. | Streamlined Authority Code 12565 |
| C12566 | P12566 | CN12566 | Gemtuzumab ozogamicin | Acute Myeloid Leukaemia<br>Consolidation treatment<br>Patient must have achieved a complete remission following induction treatment with this drug for this condition; AND<br>The treatment must be in combination with standard intensive remission consolidation chemotherapy for this condition, which must include cytarabine and an anthracycline; AND<br>Patient must not receive more than 2 consolidation cycles under this restriction in a lifetime.<br>This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.<br>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.<br>Complete remission following induction is defined as fewer than 5% blasts in a normocellular marrow and an absolute neutrophil count of more than 1.0 x $10^9$ cells/L with a platelet count of 100 x $10^9$/L or more in the peripheral blood in the absence of transfusion.<br>Progressive disease is defined as the presence of any of the following | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | a) Leukaemic cells in the CSF;<br>b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;<br>c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;<br>d) Extramedullary leukaemia. | |
| C12567 | P12567 | CN12567 | Methoxsalen | Chronic graft versus host disease<br>Continuing treatment<br>Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both:<br>(i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment; AND<br>Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode; AND<br>Must be treated by a haematologist; or<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition; AND<br>Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse. | Compliance with Authority Required procedures - Streamlined Authority Code 12567 |
| C12569 | P12569 | CN12569 | Nilotinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - third-line therapy<br>The condition must be in the chronic phase; or<br>The condition must be in the accelerated phase; AND<br>Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting; or | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have failed PBS-subsidised treatment with this drug for this condition in the second-line setting; AND<br>Patient must have documented failure with an adequate trial of PBS-subsidised first-line treatment with imatinib for this condition; AND<br>Patient must have failed an adequate trial of PBS-subsidised second-line treatment with dasatinib for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition.<br>Failure of an adequate trial of dasatinib is defined as:<br>(i) Lack of response to second-line dasatinib therapy, defined as either:<br>(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib therapy; OR<br>(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib therapy; OR<br>(iv) Development of accelerated phase in a patient previously prescribed dasatinib for the chronic phase of chronic myeloid leukaemia.<br>Accelerated phase is defined by the presence of 1 or more of the following:<br>(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or<br>(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or<br>(3) Peripheral basophils greater than or equal to 20%; or<br>(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or<br>(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR | |

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

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.<br>Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.<br>A bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale either on peripheral blood or bone marrow must be documented in the patient's medical records.<br>Pathology report(s) confirming a loss of response to imatinib 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. | |
| C12570 | P12570 | CN12570 | Dasatinib | Chronic Myeloid Leukaemia (CML)<br>Initial treatment - first-line therapy<br>Patient must have a primary diagnosis of chronic myeloid leukaemia; AND<br>The condition must be in the chronic phase; AND<br>The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; or<br>The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR); AND<br>Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first-line therapy for this condition; AND<br>The treatment must not exceed a total maximum of 18 months of therapy with PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures |

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| | | | | 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.<br>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.<br>A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.<br>The expression of the Philadelphia chromosome should be confirmed through cytogenetic analysis by standard karyotyping; or if standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be documented in the patient's medical records. | |
| C12572 | P12572 | CN12572 | Nilotinib | Chronic Myeloid Leukaemia (CML)<br>Continuing treatment - first-line therapy<br>The condition must be in the chronic phase; AND<br>Patient must have received initial PBS-subsidised treatment with this drug as a first-line therapy for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with imatinib for this condition; or<br>Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised first-line treatment with dasatinib for this condition; AND<br>Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; or<br>Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12572 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12576 | P12576 | CN12576 | Vedolizumab | Severe Crohn disease<br>Initial treatment with subcutaneous form<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 1 (new patient); or<br>Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years); or<br>Patient must have received at least 2 of the 3 initial intravenous infusions with this drug for this condition at weeks 0, 2 and 6 under Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years); or<br>Patient must have a concurrent authority application for the intravenous infusion for this condition under either 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); AND<br>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment;<br>Patient must be aged 18 years or older.<br>Where two initial doses of vedolizumab (at weeks 0 and 2) are administered via intravenous infusion, initial treatment with subcutaneous form will commence at week 6. The maximum listed quantity and 2 repeats should be requested to provide for weeks 6, 8, 10, 12, 14 and 16.<br>Where three initial doses of vedolizumab (at weeks 0, 2 and 6) is administered via intravenous infusion, initial treatment with subcutaneous form will commence at | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | week 14 (8 weeks after the third dose). A maximum quantity with no repeats should be requested to provide for weeks 14 and 16.<br>The authority application must be made in writing and must include<br>(a) a completed authority prescription form(s); and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.<br>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |
| C12579 | P12579 | CN12579 | Methoxsalen | Chronic graft versus host disease<br>Initial treatment in a treatment episode<br>The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; or<br>The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; or<br>The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed; AND<br>Patient must be undergoing treatment with this drug that is being administered within at least one of: | Compliance with Authority Required procedures - Streamlined Authority Code 12579 |

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| | | | | (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25th dose) of a treatment episode; AND<br>Must be treated by a haematologist; or<br>Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or<br>Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types; AND<br>Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation; AND<br>Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition. | |
| C12585 | P12585 | CN12585 | Siltuximab | Idiopathic multicentric Castleman disease (iMCD)<br>Initial treatment<br>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<br>The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD:<br>(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<br>Must be treated by a haematologist; or<br>Must be treated by a medical physician working under the supervision of a haematologist; AND<br>Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed. or<br>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.<br>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 |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| C12588 | P12588 | CN12588 | Somatropin | Severe growth hormone deficiency<br>Initial treatment of late onset growth hormone deficiency<br>Must be treated by an endocrinologist; AND<br>Patient must have onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease diagnosed at chronological age of 18 years or older; or<br>Patient must have onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years; AND<br>Patient must have a diagnostic insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre. or<br>Patient must have a diagnostic arginine infusion test with maximum serum GH less than 0.4 micrograms per litre. or<br>Patient must have a diagnostic glucagon provocation test with maximum serum GH less than 3 micrograms per litre.<br>The authority application must be in writing and must include:<br>A completed authority prescription form; AND<br>A completed Severe Growth Hormone Deficiency supporting information form; AND<br>Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender. | Compliance with Written Authority Required procedures |
| C12590 | P12590 | CN12590 | Olaparib | Castration resistant metastatic carcinoma of the prostate<br>Initial treatment<br>The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND<br>The treatment must not be subsidised in combination with:<br>(i) chemotherapy, (ii) a novel hormonal drug; AND<br>The condition must have progressed following prior treatment that included a novel hormonal drug for this condition (metastatic/non-metastatic disease); AND<br>Patient must have a WHO performance status of 2 or less; AND<br>Patient must be undergoing treatment with this drug for the first time. | Compliance with Authority Required procedures |

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| C12594 | P12594 | CN12594 | Siltuximab | Idiopathic multicentric Castleman disease (iMCD)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>Must be treated by a haematologist. or<br>Must be treated by a medical physician working under the supervision of a haematologist.<br>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<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>The treatment must not be subsidised in combination with:<br>(i) chemotherapy, (ii) a novel hormonal drug. | Compliance with Authority Required procedures |
| C12599 | P12599 | CN12599 | Tiotropium | Severe asthma<br>Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of:<br>(i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique; AND<br>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;<br>Patient must be at least 18 years of age.<br>Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist. | |

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| C12603 | P12603 | CN12603 | Beclometasone with formoterol and glycopyrronium<br>Fluticasone furoate with umeclidinium and vilanterol<br>Indacaterol with glycopyrronium and mometasone | Severe asthma<br>Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of:<br>(i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique;<br>Patient must be at least 18 years of age.<br>Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist. | Compliance with Authority Required procedures - Streamlined Authority Code 12603 |
| C12604 | P12604 | CN12604 | Ivermectin | Human sarcoptic scabies<br>The condition must be established by clinical and/or parasitological examination;<br>Patient must identify as Aboriginal or Torres Strait Islander;<br>Patient must weigh 15 kg or over;<br>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<br>The condition must affect the ileum. or<br>The condition must affect the ascending colon. or<br>The condition must affect the ileum and ascending colon.<br>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 |
| C12609 | P12609 | CN12609 | Tezacaftor with ivacaftor and ivacaftor | Cystic fibrosis - one residual function (RF) mutation<br>Continuing treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures |

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| | | | | The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition;<br>Patient must be 12 years of age or older.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.<br>Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers<br>Strong CYP3A4 inducers avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;<br>Moderate CYP3A4 inducers bosentan, efavirenz, etravirine, modafinil, nafcillin;<br>Weak CYP3A4 inducers armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| C12614 | P12614 | CN12614 | Tezacaftor with ivacaftor and ivacaftor | Cystic fibrosis - homozygous for the F508del mutation<br>Continuing treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition;<br>Patient must be 12 years of age or older.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.<br>Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers<br>Strong CYP3A4 inducers avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;<br>Moderate CYP3A4 inducers bosentan, efavirenz, etravirine, modafinil, nafcillin;<br>Weak CYP3A4 inducers armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| C12619 | P12619 | CN12619 | Cabotegravir | HIV infection | Compliance with Authority Required |

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| | | | | Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND<br>The treatment must be in combination with rilpivirine tablets; AND<br>Patient must intend to proceed to treatment with intramuscular administration of cabotegravir and rilpivirine. | procedures - Streamlined Authority Code 12619 |
| C12624 | P12624 | CN12624 | Ivacaftor | Cystic fibrosis<br>Initial treatment - New patients<br>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND<br>Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; or<br>Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele; AND<br>Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>The treatment must be given concomitantly with standard therapy for this condition;<br>Patient must be aged 12 months or older.<br>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.<br>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a | Compliance with Authority Required procedures |

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| | | | | patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.<br>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.<br>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers<br>Strong CYP3A4 inducers avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort<br>Moderate CYP3A4 inducers bosentan, efavirenz, etravirine, modafinil, nafcillin<br>Weak CYP3A4 inducers armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and<br>(3) details of the pathology report substantiating G551D mutation or other gating (class III) mutation on the CFTR gene - quote each of the (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and<br>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and<br>(5) sweat chloride result. | |
| C12625 | P12625 | CN12625 | Ivacaftor | Cystic fibrosis<br>Continuing treatment<br>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND<br>Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>The treatment must be given concomitantly with standard therapy for this condition;<br>Patient must be aged 12 months or older. | Compliance with Authority Required procedures |

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| | | | | Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.<br>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.<br>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.<br>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers<br>Strong CYP3A4 inducers avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort<br>Moderate CYP3A4 inducers bosentan, efavirenz, etravirine, modafinil, nafcillin<br>Weak CYP3A4 inducers armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| C12630 | P12630 | CN12630 | Tezacaftor with ivacaftor and ivacaftor | Cystic fibrosis - one residual function (RF) mutation<br>Initial treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND | Compliance with Authority Required procedures |

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| | | | | Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities;<br>Patient must be 12 years of age or older.<br>For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.<br>Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers<br>Strong CYP3A4 inducers avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;<br>Moderate CYP3A4 inducers bosentan, efavirenz, etravirine, modafinil, nafcillin;<br>Weak CYP3A4 inducers armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and | |

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| | | | | (3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and<br>(4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| C12635 | P12635 | CN12635 | Tezacaftor with ivacaftor and ivacaftor | Cystic fibrosis - homozygous for the F508del mutation<br>Initial treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities;<br>Patient must be 12 years of age or older.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. | Compliance with Authority Required procedures |

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| | | | | Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers<br>Strong CYP3A4 inducers avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;<br>Moderate CYP3A4 inducers bosentan, efavirenz, etravirine, modafinil, nafcillin;<br>Weak CYP3A4 inducers armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and<br>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and<br>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| C12636 | P12636 | CN12636 | Cabotegravir and rilpivirine | HIV infection<br>Patient must have previously received PBS-subsidised therapy for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12636 |
| C12639 | P12639 | CN12639 | Onasemnogene abeparvovec | Spinal muscular atrophy (SMA)<br>Use in a patient untreated with disease modifying therapies for this condition<br>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or<br>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND<br>Patient must have experienced at least two of the defined signs/symptoms of Type 1 SMA specified below; or<br>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND<br>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. | Compliance with Authority Required procedures |

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| | | | | ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND<br>The treatment must be given concomitantly with best supportive care for this condition; AND<br>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND<br>Must be treated in a treatment centre that is each of:<br>(i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing; AND<br>Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime; AND<br>Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of:<br>(i) nusinersen, (ii) risdiplam;<br>Patient must be no older than 9 months of age;<br>Patient must have symptomatic Type 1 SMA. or<br>Patient must have pre-symptomatic SMA.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>Prescribing Instructions:<br>In the relevant PBS Authority Application form, specify the following:<br>(i) the SMA type being treated: symptomatic Type 1 SMA, or, pre-symptomatic SMA;<br>(ii) for Type 1 SMA, the signs/symptoms that the patient has experienced, together with the patient's age at the onset of these signs/symptoms.<br>(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or | |

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| | | | | (ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.<br>State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.<br>Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:<br>(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or<br>(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.<br>If the condition is pre-symptomatic SMA, confirm that there is genetic test finding that substantiates the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).<br>Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.<br>Defined signs and symptoms of type I SMA are<br>i) Onset before 6 months of age; and<br>ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or<br>iii) Proximal weakness; or<br>iv) Hypotonia; or<br>v) Absence of deep tendon reflexes; or<br>vi) Failure to gain weight appropriate for age; or<br>vii) Any active chronic neurogenic changes; or<br>viii) A compound muscle action potential below normative values for an age-matched child. | |
| C12656 | P12656 | CN12656 | Sacituzumab govitecan | Unresectable locally advanced or metastatic triple-negative breast cancer<br>Initial treatment<br>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<br>The condition must be inoperable; AND | Compliance with Authority Required procedures - Streamlined Authority Code 12656 |

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| | | | | 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<br>The treatment must be the sole PBS-subsidised therapy for this PBS indication. | |
| C12669 | P12669 | CN12669 | Sacituzumab govitecan | Unresectable locally advanced or metastatic triple-negative breast cancer<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while being treated with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this PBS indication. | Compliance with Authority Required procedures - Streamlined Authority Code 12669 |
| C12672 | P12672 | CN12672 | Nusinersen | Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)<br>Initial treatment - Loading doses<br>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND<br>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or<br>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND<br>Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age; AND<br>The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND<br>The treatment must be given concomitantly with best supportive care for this condition; AND<br>The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND<br>Patient must be untreated with gene therapy;<br>Patient must be 18 years of age or under. | Compliance with Authority Required procedures |

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

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| | | | | vii) Any active chronic neurogenic changes; or<br>viii) A compound muscle action potential below normative values for an age-matched child.<br>Application for authorisation of initial treatment must be in writing and must include<br>(a) a completed authority prescription form; and<br>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following<br>(ii) sign(s) and symptom(s) that the patient has experienced; and<br>(iii) patient's age at the onset of sign(s) and symptom(s).<br>i) specification of SMA type (I, II or IIIa); and<br>(ii) sign(s) and symptom(s) that the patient has experienced; and<br>(iii) patient's age at the onset of sign(s) and symptom(s). | |
| C12676 | P12676 | CN12676 | Nusinersen | Spinal muscular atrophy (SMA)<br>Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with one of: (i) Type 1 SMA, or, (ii) pre-symptomatic SMA<br>Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this:<br>(i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples); AND<br>The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes; AND<br>The treatment must be given concomitantly with best supportive care for this condition; AND<br>The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND<br>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical | Compliance with Authority Required procedures |

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| | | | | practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND<br>Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type;<br>Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy. or<br>Patient must have a prior authority approval for any drug PBS-listed for pre-symptomatic SMA, with at least one approval having been for gene therapy.<br>The authority application must be made in writing and must include<br>(1) a completed authority prescription form; and<br>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).<br>Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.<br>Confirm that a previous PBS authority application has been approved for one of the following<br>(i) Symptomatic Type 1 SMA; or<br>(ii) Pre-symptomatic SMA treated with nusinersen.<br>Definition<br>Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.<br>0. Absence of developmental states (1 to 9) listed below<br>1. Rolls from side to side on back;<br>2. Child holds head erect for at least 3 seconds unsupported;<br>3. Sitting, but with assistance;<br>4. Sitting without assistance<br>(a) Child sits up straight with the head erect for at least 10 seconds;<br>(b) Child does not use arms or hands to balance body or support position.<br>5. Hands and knees crawling | |

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| | | | | (a) Child alternately moves forward or backwards on hands and knees;<br>(b) The stomach does not touch the supporting surface;<br>(c) There are continuous and consecutive movements at least 3 in a row.<br>6. Standing with assistance<br>(a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;<br>(b)The body does not touch the stable object, and the legs support most of the body weight;<br>(c) Child thus stands with assistance for at least 10 seconds.<br>7. Standing alone<br>(a) Child stands in upright position on both feet (not on the toes) with the back straight;<br>(b) The leg supports 100% of the child's weight;<br>(c) There is no contact with a person or object;<br>(d) Child stands alone for at least 10 seconds.<br>8. Walking with assistance<br>(a) Child is in an upright position with the back straight;<br>(b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;<br>(c) One leg moves forward while the other supports part of the body weight;<br>(d) Child takes at least 5 steps in this manner.<br>9. Walking alone<br>(a) Child takes at least 5 steps independently in upright position with the back straight;<br>(b) One leg moves forward while the other supports most of the body weight;<br>(c) There is no contact with a person or object.<br>Confirm which developmental state has regressed by (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i).<br>Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available. | |

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| C12685 | P12685 | CN12685 | Imatinib | Malignant gastrointestinal stromal tumour<br>Initial treatment<br>The condition must be metastatic; or<br>The condition must be unresectable; AND<br>The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining; AND<br>The condition must have not achieved a response with this drug at a dose of 400 mg per day; AND<br>The treatment must not exceed 3 months under this restriction.<br>Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.<br>Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.<br>A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347 472-80.)<br>A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.<br>Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.<br>Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records. | Compliance with Authority Required procedures |

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| C12691 | P12691 | CN12691 | Daratumumab | Relapsed and/or refractory multiple myeloma<br>Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or<br>(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<br>(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<br>(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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>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<br>Initial treatment - once weekly treatment regimen<br>The condition must be confirmed by a histological diagnosis; AND<br>The treatment must be in combination with dexamethasone; AND<br>Patient must have progressive disease after at least one prior therapy; AND<br>Patient must have undergone or be ineligible for a stem cell transplant; AND | Compliance with Authority Required procedures - Streamlined Authority Code 12694 |

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| | | | | Patient must not have previously received this drug for this condition; AND<br>Patient must not receive more than three cycles of treatment under this restriction.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or<br>(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<br>(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<br>(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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | |
| C12703 | P12703 | CN12703 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Continuing treatment<br>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<br>Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent | Compliance with Authority Required procedures |

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| | | | | treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more. or<br>Patient must be female and must not have a bone age of 13.5 years or more.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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.<br>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. | |
| C12704 | P12704 | CN12704 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Initial treatment<br>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<br>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<br>Patient must have a current height at or below the 1$^{st}$ percentile for age and sex; AND<br>Patient must have a growth velocity below the 25$^{th}$ percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or<br>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<br>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 | Compliance with Authority Required procedures |

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| | | | | 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. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The most recent data must not be more than three months old at the time of application; AND<br>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<br>5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND<br>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<br>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).<br>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.<br>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. | |
| C12705 | P12705 | CN12705 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome<br>Initial treatment<br>Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); or<br>Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND<br>Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; or<br>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<br>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 | Compliance with Authority Required procedures |

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| | | | | 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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must not have a chronological age of 18 years or greater; AND<br>Must be treated by a specialist or consultant physician in paediatric endocrinology.<br>or<br>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>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<br>5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR | |

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| | | | | (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist<br>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<br>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)<br>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.<br>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. | |
| C12711 | P12711 | CN12711 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 | Compliance with Authority Required procedures |

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| | | | | 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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a chronological age of 5 years or greater; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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).<br>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.<br>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. | |
| C12712 | P12712 | CN12712 | Somatropin | Short stature associated with Turner syndrome<br>Recommencement of treatment as a reclassified patient<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics; AND<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 | Compliance with Authority Required procedures |

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| | | | | 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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a height greater than or equal to 155.0 cm; AND<br>Patient must not have a bone age of 13.5 years or greater.<br>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). | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>3. A height measurement from immediately prior to commencement of growth hormone treatment; AND<br>4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND<br>5. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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.<br>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. | |
| C12713 | P12713 | CN12713 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Initial treatment<br>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<br>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<br>Patient must be female and menarche occurred before the chronological age of 10 years; AND<br>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 | Compliance with Authority Required procedures |

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| | | | | to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); or<br>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<br>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<br>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<br>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<br>Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND | |

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| | | | | Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older;<br>Must be treated by a specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>(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<br>4. A bone age result performed within the last 12 months; AND<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>6. Confirmation that the patient has precocious puberty; AND<br>7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND | |

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| | | | | 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).<br>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.<br>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. | |
| C12721 | P12721 | CN12721 | Somatropin | Short stature associated with chronic renal insufficiency<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have had a height at or below the 1$^{st}$ percentile for age and sex immediately prior to commencing treatment; or<br>Patient must have had both a height above the 1$^{st}$ and at or below the 25$^{th}$ percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25$^{th}$ 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<br>Patient must have had both a height above the 1$^{st}$ and at or below the 25$^{th}$ 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<br>Patient must have had both a height above the 1$^{st}$ and at or below the 25$^{th}$ 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<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ 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 | |

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| | | | | Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>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 | |

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| | | | | of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR<br>(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<br>4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND<br>5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND<br>6. Recent growth data (height and weight, not older than three months); AND<br>7. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12722 | P12722 | CN12722 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Initial treatment<br>Patient must have had an intracranial lesion which is under appropriate observation and management; or<br>Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND<br>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<br>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 | Compliance with Authority Required procedures |

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| | | | | 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<br>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<br>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<br>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<br>Patient must have a current height at or below the 1st percentile for age and sex; or<br>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<br>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<br>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 | |

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| | | | | Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>(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 | |

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| | | | | 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<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>6. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR<br>(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND<br>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).<br>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.<br>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. | |
| C12723 | P12723 | CN12723 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Initial treatment<br>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<br>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<br>Patient must be female and menarche occurred before the chronological age of 10 years; AND<br>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 | Compliance with Authority Required procedures |

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| | | | | 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<br>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<br>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<br>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<br>Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND | |

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| | | | | Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>(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<br>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<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>6. Confirmation that the patient has precocious puberty; AND<br>7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND<br>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). | |

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| | | | | 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.<br>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. | |
| C12725 | P12725 | CN12725 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 | Compliance with Authority Required procedures |

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| | | | | 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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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. | |

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| | | | | 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. | |
| C12726 | P12726 | CN12726 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND | Compliance with Authority Required procedures |

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| | | | | Patient must have had an intracranial lesion which is under appropriate observation and management; or<br>Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND<br>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<br>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<br>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<br>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<br>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 | |

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| | | | | Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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 | |

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| | | | | required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>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<br>(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<br>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR<br>(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND<br>6. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12731 | P12731 | CN12731 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Continuing treatment<br>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<br>Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be male and must not have a bone age of 15.5 years or more. or<br>Patient must be female and must not have a bone age of 13.5 years or more.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>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<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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.<br>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. | |
| C12738 | P12738 | CN12738 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Recommencement of treatment as a reclassified patient | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>Patient must have had a lapse in treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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 | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | appropriate plan of management in place for the patient's increased risk of gonadoblastoma; AND<br>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND<br>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<br>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<br>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<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>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<br>4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND<br>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<br>6. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12749 | P12749 | CN12749 | Somatropin | Short stature associated with chronic renal insufficiency<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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<br>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<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ 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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>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<br>(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1$^{st}$ percentile for age and sex immediately prior to commencing treatment; AND<br>4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m$^2$ ; AND<br>5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND | |

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| | | | | 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<br>7. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12752 | P12752 | CN12752 | Somatropin | Short stature associated with chronic renal insufficiency<br>Recommencement of treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND<br>Patient must not have an eGFR equal to or greater than 30mL/min/1.73$m^2$; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;<br>Patient must be aged 3 years or older.<br>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 | |

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| | | | | required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>4. A bone age result performed within the last 12 months; AND<br>5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND<br>6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND<br>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).<br>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.<br>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/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.<br>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. | |
| C12755 | P12755 | CN12755 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Initial treatment<br>Patient must have had an intracranial lesion which is under appropriate observation and management; or<br>Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND | Compliance with Authority Required procedures |

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| | | | | 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 | |

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| | | | | 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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older;<br>Must be treated by a specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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 | |

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| | | | | (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<br>4. A bone age result performed within the last 12 months; AND<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>6. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR<br>(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND<br>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).<br>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.<br>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. | |
| C12758 | P12758 | CN12758 | Somatropin | Short stature associated with Turner syndrome<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a bone age of 13.5 years or greater; AND<br>Patient must not have a height greater than or equal to 155.0 cm; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or | |

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| | | | | Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>3. A height measurement from immediately prior to commencement of growth hormone treatment; AND<br>4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND<br>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<br>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<br>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).<br>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.<br>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. | |

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| C12760 | P12760 | CN12760 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of | Compliance with Authority Required procedures |

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| | | | | 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<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>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<br>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). | |

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| | | | | 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.<br>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. | |
| C12765 | P12765 | CN12765 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Initial treatment<br>Patient must have a structural lesion that is not neoplastic; or<br>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<br>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<br>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<br>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<br>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 | Compliance with Authority Required procedures |

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| | | | | 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<br>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<br>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<br>Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND<br>Patient must have hypothalamic obesity; AND<br>Patient must have a growth velocity above the 25$^{th}$ percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a specialist or consultant physician in paediatric endocrinology.<br>or | |

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| | | | | Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>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<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR<br>(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<br>(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<br>7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND | |

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| | | | | 8. Confirmation that the patient has hypothalamic obesity; AND<br>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).<br>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.<br>Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.<br>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. | |
| C12768 | P12768 | CN12768 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome<br>Continuing treatment<br>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<br>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<br>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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies; or<br>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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or | Compliance with Authority Required procedures |

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| | | | | recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies; or<br>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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies; or<br>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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>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 | |

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| | | | | 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<br>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<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND | |

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| | | | | 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;<br>Patient must not have a chronological age of equal to or greater than 18 years.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>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<br>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<br>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).<br>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.<br>Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations). | |

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| | | | | 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. | |
| C12769 | P12769 | CN12769 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have had an intracranial lesion which is under appropriate observation and management; or | Compliance with Authority Required procedures |

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| | | | | Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND<br>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<br>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<br>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<br>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<br>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<br>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or | |

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| | | | | 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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>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<br>(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<br>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR<br>(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND<br>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<br>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<br>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).<br>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.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12770 | P12770 | CN12770 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have a structural lesion that is not neoplastic; or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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<br>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<br>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<br>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<br>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<br>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 | |

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| | | | | (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND<br>Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND<br>Patient must have hypothalamic obesity; AND<br>Patient must have had a growth velocity above the 25$^{th}$ 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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>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<br>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR<br>(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<br>(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<br>6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND<br>7. Confirmation that the patient has hypothalamic obesity; AND<br>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<br>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<br>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). | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>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. | |
| C12771 | P12771 | CN12771 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND<br>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<br>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<br>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<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND | |

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| | | | | Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>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<br>4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND<br>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<br>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<br>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 | |

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| | | | | 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).<br>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.<br>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. | |
| C12774 | P12774 | CN12774 | Somatropin | Short stature associated with Turner syndrome<br>Recommencement of treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>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<br>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). | |

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| | | | | 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.<br>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. | |
| C12775 | P12775 | CN12775 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or | Compliance with Authority Required procedures |

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| | | | | The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have a chronological age of less than 2 years; AND<br>Patient must have a documented clinical risk of hypoglycaemia; AND<br>Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND<br>4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND<br>5. Recent growth data (height and weight, not older than three months); AND | |

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| | | | | 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).<br>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.<br>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. | |
| C12779 | P12779 | CN12779 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Continuing treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category; AND<br>Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more. or<br>Patient must be female and must not have a bone age of 13.5 years or more.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>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<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12780 | P12780 | CN12780 | Somatropin | Short stature associated with Turner syndrome<br>Continuing treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND<br>Patient must not have been on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND | Compliance with Authority Required procedures |

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| | | | | Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a bone age of 13.5 years or greater; AND<br>Patient must not have a height greater than or equal to 155.0 cm.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>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<br>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).<br>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.<br>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. | |
| C12784 | P12784 | CN12784 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Recommencement of treatment | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or | |
| | | | | The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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 | |

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| | | | | Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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.<br>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. | |
| C12785 | P12785 | CN12785 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Recommencement of treatment as a reclassified patient<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | disease secondary to a structural lesion, with hypothalamic obesity driven growth; AND<br>Patient must have had a lapse in treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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 | |

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| | | | | 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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND | |

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| | | | | 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>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<br>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR<br>(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<br>(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<br>6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND<br>7. Confirmation that the patient has hypothalamic obesity; AND<br>8. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12789 | P12789 | CN12789 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have a structural lesion that is not neoplastic; or | Compliance with Authority Required procedures |

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| | | | | 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<br>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<br>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<br>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<br>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<br>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<br>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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND<br>Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND<br>Patient must have hypothalamic obesity; AND<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The maximum duration of each continuing treatment phase is 26 weeks.<br>Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the *National Health (Growth Hormone Program)* | |

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| | | | | *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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>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<br>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR<br>(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<br>(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<br>6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND<br>7. Confirmation that the patient has hypothalamic obesity; AND<br>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<br>9. A bone age result performed within the last 12 months; AND<br>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). | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>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. | |
| C12790 | P12790 | CN12790 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND<br>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<br>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<br>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<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>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<br>4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND<br>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<br>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<br>7. A bone age result performed within the last 12 months; AND | |

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| | | | | 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).<br>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.<br>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. | |
| C12791 | P12791 | CN12791 | Somatropin | Short stature associated with chronic renal insufficiency<br>Initial treatment<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ 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<br>Patient must have a current height at or below the 1$^{st}$ percentile for age and sex; or<br>Patient must have a current height above the 1$^{st}$ and at or below the 25$^{th}$ percentiles for age and sex and a growth velocity less than or equal to the 25$^{th}$ percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or<br>Patient must have a current height above the 1$^{st}$ and at or below the 25$^{th}$ 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<br>Patient must have a current height above the 1$^{st}$ and at or below the 25$^{th}$ 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 | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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 | |

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| | | | | (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<br>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<br>5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND<br>6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND<br>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).<br>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.<br>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. | |
| C12793 | P12793 | CN12793 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; or<br>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 | |

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| | | | | 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<br>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<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>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 | |

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| | | | | weight derived by calculating the 50th percentile weight for the patient's current height;<br>Patient must not have a chronological age of equal to or greater than 18 years;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height, weight, and waist circumference, not older than three months); AND<br>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<br>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<br>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).<br>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. | |

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| | | | | 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. | |
| C12798 | P12798 | CN12798 | Somatropin | Short stature associated with chronic renal insufficiency<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or<br>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<br>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<br>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<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ 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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND | |

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| | | | | Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>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<br>(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<br>4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73$m^2$ ; AND<br>5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND<br>6. Recent growth data (height and weight, not older than three months); AND | |

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| | | | | 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<br>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).<br>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.<br>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. | |
| C12803 | P12803 | CN12803 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants<br>Initial treatment<br>Must be treated by a specialist or consultant physician in paediatric endocrinology; or<br>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<br>Patient must have a chronological age of less than 2 years; AND<br>Patient must have a documented clinical risk of hypoglycaemia; AND<br>Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.<br>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* | Compliance with Authority Required procedures |

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| | | | | *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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND<br>5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND<br>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).<br>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.<br>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. | |
| C12805 | P12805 | CN12805 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants<br>Continuing treatment<br>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<br>Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or | Compliance with Authority Required procedures |

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| | | | | Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a chronological age of 5 years or greater;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND | |

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| | | | | 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<br>4. A bone age result performed within the last 12 months; AND<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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.<br>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'.<br>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. | |
| C12806 | P12806 | CN12806 | Somatropin | Short stature associated with chronic renal insufficiency<br>Continuing treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND<br>Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND<br>Patient must not have an eGFR equal to or greater than 30mL/min/1.73m$^2$; AND<br>Patient must be male and must not have a height greater than or equal to 167.7 cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>4. A bone age result performed within the last 12 months; AND<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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.<br>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. | |
| C12809 | P12809 | CN12809 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a chronological age of 5 years or greater; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>4. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12810 | P12810 | CN12810 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have had an intracranial lesion which is under appropriate observation and management; or<br>Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND<br>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<br>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<br>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 | |

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| | | | | 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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>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<br>(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<br>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR | |

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| | | | | (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND<br>6. Recent growth data (height and weight, not older than three months); AND<br>7. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12812 | P12812 | CN12812 | Somatropin | Short stature associated with chronic renal insufficiency<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have had a height at or below the 1$^{st}$ percentile for age and sex immediately prior to commencing treatment; or<br>Patient must have had both a height above the 1$^{st}$ and at or below the 25$^{th}$ percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25$^{th}$ 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<br>Patient must have had both a height above the 1$^{st}$ and at or below the 25$^{th}$ 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<br>Patient must have had both a height above the 1$^{st}$ and at or below the 25$^{th}$ 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<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal | |

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| | | | | transplant, and have undergone a 12 month period of observation following the transplant; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>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 | |

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| | | | | of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR<br>(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<br>4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m$^2$ ; AND<br>5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND<br>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<br>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<br>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).<br>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.<br>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. | |
| C12817 | P12817 | CN12817 | Somatropin | Short stature associated with Turner syndrome<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or | Compliance with Authority Required procedures |

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| | | | | The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have a height greater than or equal to 155.0 cm;<br>Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>3. A height measurement from immediately prior to commencement of growth hormone treatment; AND<br>4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND<br>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<br>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<br>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).<br>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. | |

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| | | | | 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. | |
| C12820 | P12820 | CN12820 | Somatropin | Short stature associated with Turner syndrome<br>Recommencement of treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12821 | P12821 | CN12821 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must have a structural lesion that is not neoplastic; or<br>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<br>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<br>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<br>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<br>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<br>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<br>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 | |

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| | | | | (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels; AND<br>Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND<br>Patient must have hypothalamic obesity; AND<br>Patient must have had a growth velocity above the 25$^{th}$ 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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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)* | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | *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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>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<br>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR<br>(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<br>(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<br>6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND<br>7. Confirmation that the patient has hypothalamic obesity; AND<br>8. Recent growth data (height and weight, not older than three months); AND<br>9. A bone age result performed within the last 12 months; AND<br>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).<br>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 | |

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| | | | | 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.<br>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. | |
| C12824 | P12824 | CN12824 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm;<br>Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND | |

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| | | | | 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>4. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12826 | P12826 | CN12826 | Somatropin | Short stature associated with Turner syndrome<br>Initial treatment<br>Must be treated by a specialist or consultant physician in paediatric endocrinology; or<br>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<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND | Compliance with Authority Required procedures |

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| | | | | Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must not have a height greater than or equal to 155.0 cm; AND<br>Patient must not have a bone age of 13.5 years or greater;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>(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<br>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<br>5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND<br>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).<br>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 | |

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| | | | | be kept for 2 years after the date the prescription to which the records relate is written.<br>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. | |
| C12829 | P12829 | CN12829 | Somatropin | Short stature associated with chronic renal insufficiency<br>Recommencement of treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND<br>Patient must not have an eGFR equal to or greater than 30mL/min/1.73m$^2$; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>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 | |

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| | | | | 5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND<br>6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND<br>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).<br>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.<br>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/1.73m$^2$ prescribers should seek reclassification to the indication short stature and slow growth.<br>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. | |
| C12831 | P12831 | CN12831 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants<br>Continuing treatment<br>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<br>Patient must not have been on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or | Compliance with Authority Required procedures |

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| | | | | Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a chronological age of 5 years or greater.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>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 | |

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| | | | | 5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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.<br>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'.<br>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. | |
| C12832 | P12832 | CN12832 | Somatropin | Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have a chronological age of less than 2 years; AND<br>Patient must have a documented clinical risk of hypoglycaemia; AND<br>Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND | |

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| | | | | 3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND<br>4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND<br>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<br>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).<br>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.<br>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. | |
| C12834 | P12834 | CN12834 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Continuing treatment<br>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<br>Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or | Compliance with Authority Required procedures |

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| | | | | recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7 cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more. or<br>Patient must be female and must not have a bone age of 13.5 years or more.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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 | |

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| | | | | 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<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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.<br>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. | |
| C12842 | P12842 | CN12842 | Daratumumab | Relapsed and/or refractory multiple myeloma<br>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements<br>Patient must have been on treatment with this drug in the subcutaneous form for this condition prior to 1 November 2021; AND<br>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:<br>(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<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>Progressive disease is defined as at least 1 of the following | Compliance with Authority Required procedures |

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| | | | | (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or<br>(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<br>(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<br>(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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.<br>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.<br>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<br>(a) the level of serum monoclonal protein; or<br>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or<br>(c) the serum level of free kappa and lambda light chains; or<br>(d) bone marrow aspirate or trephine; or<br>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or<br>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or | |

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| | | | | (g) if present, the level of hypercalcaemia, corrected for albumin concentration.<br>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.<br>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.<br>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. | |
| C12844 | P12844 | CN12844 | Daratumumab | Relapsed and/or refractory multiple myeloma<br>Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply<br>Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2021; AND<br>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:<br>(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 | Compliance with Authority Required procedures |

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| | | | | Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or<br>(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<br>(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<br>(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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.<br>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.<br>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<br>(a) the level of serum monoclonal protein; or<br>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or<br>(c) the serum level of free kappa and lambda light chains; or<br>(d) bone marrow aspirate or trephine; or | |

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| | | | | (e) if present, the size and location of lytic bone lesions (not including compression fractures); or<br>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or<br>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.<br>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.<br>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.<br>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. | |
| C12845 | P12845 | CN12845 | Daratumumab | Relapsed and/or refractory multiple myeloma<br>Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with bortezomib and dexamethasone; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or | Compliance with Authority Required procedures |

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| | | | | (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<br>(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<br>(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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | |
| C12847 | P12847 | CN12847 | Elotuzumab | Relapsed and/or refractory multiple myeloma<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with lenalidomide and dexamethasone; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or<br>(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<br>(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<br>(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 | Compliance with Authority Required procedures |

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| | | | | (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | |
| C12849 | P12849 | CN12849 | Carfilzomib | Multiple myeloma<br>Continuing treatment - once weekly treatment regimen<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with dexamethasone; AND<br>Patient must not develop disease progression while receiving treatment with this drug for this condition; AND<br>Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or<br>(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<br>(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<br>(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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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 | Compliance with Authority Required procedures - Streamlined Authority Code 12849 |

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| | | | | (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | |
| C12855 | P12855 | CN12855 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Initial treatment<br>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<br>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<br>Patient must have a current height at or below the 1st percentile for age and sex; AND<br>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<br>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<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; | Compliance with Authority Required procedures |

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| | | | | Patient must be aged 3 years or older;<br>Must be treated by a specialist or consultant physician in paediatric endocrinology.<br>or<br>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>4. A bone age result performed within the last 12 months; AND<br>5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND<br>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<br>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).<br>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 | |

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| | | | | 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.<br>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. | |
| C12857 | P12857 | CN12857 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| | | | | continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND<br>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<br>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<br>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<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; | |

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| | | | | Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>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<br>4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND<br>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<br>6. Recent growth data (height and weight, not older than three months); AND<br>7. A bone age result performed within the last 12 months; AND | |

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| | | | | 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).<br>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.<br>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. | |
| C12858 | P12858 | CN12858 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or | Compliance with Authority Required procedures |

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| | | | | The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>Patient must be female and menarche occurred before the chronological age of 10 years; AND<br>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<br>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<br>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<br>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 | |

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| | | | | 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<br>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<br>Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>3. Confirmation that the patient has precocious puberty; AND<br>4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND | |

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| | | | | 5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>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<br>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<br>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).<br>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.<br>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. | |
| C12860 | P12860 | CN12860 | Somatropin | Short stature associated with Turner syndrome<br>Initial treatment<br>Must be treated by a specialist or consultant physician in paediatric endocrinology; or<br>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<br>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<br>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<br>Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of | Compliance with Authority Required procedures |

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| | | | | an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must not have a height greater than or equal to 155.0cm; AND<br>Patient must not have a bone age of 13.5 years or greater.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>(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<br>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<br>5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND<br>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). | |

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| | | | | 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.<br>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. | |
| C12861 | P12861 | CN12861 | Somatropin | Short stature associated with chronic renal insufficiency<br>Initial treatment<br>Must be treated by a specialist or consultant physician in paediatric endocrinology; or<br>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<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ 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<br>Patient must have a current height at or below the 1$^{st}$ percentile for age and sex; or<br>Patient must have a current height above the 1$^{st}$ and at or below the 25$^{th}$ percentiles for age and sex and a growth velocity less than or equal to the 25$^{th}$ percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or<br>Patient must have a current height above the 1$^{st}$ and at or below the 25$^{th}$ 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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND | Compliance with Authority Required procedures |

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| | | | | 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 1$^{st}$ 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/1.73m$^2$ ; AND | |

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| | | | | 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND<br>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).<br>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.<br>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. | |
| C12866 | P12866 | CN12866 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or | Compliance with Authority Required procedures |

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| | | | | The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>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 | |

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| | | | | 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).<br>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.<br>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. | |
| C12867 | P12867 | CN12867 | Somatropin | Short stature associated with chronic renal insufficiency<br>Continuing treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period | Compliance with Authority Required procedures |

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| | | | | (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application; AND<br>Patient must not have an eGFR equal to or greater than 30mL/min/1.73m$^2$; AND<br>Patient must be male and must not have a height greater than or equal to 167.7 cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more. or<br>Patient must be female and must not have a bone age of 13.5 years or more.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>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<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND | |

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| | | | | 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).<br>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.<br>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. | |
| C12869 | P12869 | CN12869 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); or<br>Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND<br>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<br>Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; or<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a chronological age of 18 years or greater; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR<br>(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND<br>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<br>5. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12871 | P12871 | CN12871 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Continuing treatment<br>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<br>Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>4. A bone age result performed within the last 12 months; AND<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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.<br>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. | |
| C12872 | P12872 | CN12872 | Somatropin | Short stature due to short stature homeobox (SHOX) gene disorders<br>Continuing treatment<br>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 | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>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<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a height greater than or equal to 167.7 cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0 cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older.<br>The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>4. A bone age result performed within the last 12 months; AND<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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.<br>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. | |
| C12876 | P12876 | CN12876 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 | Compliance with Authority Required procedures |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), 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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>4. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12877 | P12877 | CN12877 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>Patient must be female and menarche occurred before the chronological age of 10 years; AND<br>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<br>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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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<br>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<br>Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>3. Confirmation that the patient has precocious puberty; AND<br>4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>6. Recent growth data (height and weight, not older than three months); AND<br>7. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12880 | P12880 | CN12880 | Somatropin | Short stature associated with Turner syndrome<br>Continuing treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category; AND | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must not have been on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>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/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a bone age of 13.5 years or greater; AND<br>Patient must not have a height greater than or equal to 155.0 cm;<br>Patient must be aged 3 years or older.<br>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 | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>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<br>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).<br>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.<br>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. | |
| C12882 | P12882 | CN12882 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Recommencement of treatment<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;<br>Patient must be aged 3 years or older.<br>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 | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>4. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12884 | P12884 | CN12884 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Recommencement of treatment as a reclassified patient<br>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<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or | Compliance with Authority Required procedures |

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| | | | | The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>Patient must be female and menarche occurred before the chronological age of 10 years; AND<br>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<br>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<br>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 | |

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| | | | | (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<br>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<br>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<br>Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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 | |

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| | | | | required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>3. Confirmation that the patient has precocious puberty; AND<br>4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>6. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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.<br>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. | |
| C12886 | P12886 | CN12886 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m$^2$/week or greater for the most recent treatment period (32 | Compliance with Authority Required procedures |

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| | | | | weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>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<br>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<br>Patient must be female and menarche occurred before the chronological age of 10 years; AND<br>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 | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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<br>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<br>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<br>Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; | |

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| | | | | Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>3. Confirmation that the patient has precocious puberty; AND<br>4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>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<br>7. A bone age result performed within the last 12 months; AND<br>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).<br>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. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12887 | P12887 | CN12887 | Somatropin | Short stature and poor body composition due to Prader-Willi syndrome<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); or | Compliance with Authority Required procedures |

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| | | | | Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a chronological age of 18 years or greater; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR<br>(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND<br>4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep | |

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| | | | | disorders identified via the polysomnography that required treatment have been addressed; AND<br>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<br>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<br>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).<br>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.<br>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. | |
| C12891 | P12891 | CN12891 | Elotuzumab | Relapsed and/or refractory multiple myeloma<br>Initial treatment<br>The condition must be confirmed by a histological diagnosis; AND<br>The treatment must be in combination with lenalidomide and dexamethasone; AND<br>Patient must have progressive disease after at least one prior therapy; AND<br>Patient must have undergone or be ineligible for a stem cell transplant; AND<br>Patient must not have previously received this drug for this condition.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or<br>(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 | Compliance with Authority Required procedures |

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| | | | | (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<br>(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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | |
| C12895 | P12895 | CN12895 | Apalutamide<br>Darolutamide<br>Enzalutamide | Castration resistant non-metastatic carcinoma of the prostate<br>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<br>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<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND<br>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND<br>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<br>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<br>Patient must be undergoing concurrent treatment with androgen deprivation therapy. | Compliance with Authority Required procedures |

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| | | | | Prescribing instructions<br>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.<br>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. | |
| C12899 | P12899 | CN12899 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Continuing treatment<br>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<br>Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent | Compliance with Authority Required procedures |

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| | | | | treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>4. A bone age result performed within the last 12 months; AND<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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).<br>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. | |

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| | | | | 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. | |
| C12901 | P12901 | CN12901 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Recommencement of treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category; AND<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND<br>3. Recent growth data (height and weight, not older than three months); AND<br>4. A bone age result performed within the last 12 months; AND<br>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).<br>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. | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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. | |
| C12916 | P12916 | CN12916 | Somatropin | Short stature associated with Turner syndrome<br>Recommencement of treatment as a reclassified patient<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature asscciated with Turner syndrome; AND<br>Patient must have had a lapse in growth hormone treatment; AND<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND | Compliance with Authority Required procedures |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have a height greater than or equal to 155.0 cm; AND<br>Patient must not have a bone age of 13.5 years or greater; AND<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND<br>3. A height measurement from immediately prior to commencement of growth hormone treatment; AND | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND<br>5. Recent growth data (height and weight, not older than three months); AND<br>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<br>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).<br>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.<br>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. | |
| C12918 | P12918 | CN12918 | Somatropin | Biochemical growth hormone deficiency and precocious puberty<br>Continuing treatment<br>Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category; AND<br>Patient must not have been on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or | Compliance with Authority Required procedures |

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| | | | | Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); AND<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older.<br>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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND<br>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<br>4. A bone age result performed within the last 12 months; AND<br>5. The final adult height (in cm) of the patient's mother and father (where available); AND<br>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). | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | 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.<br>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. | |
| C12926 | P12926 | CN12926 | Somatropin | Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth<br>Initial treatment<br>Must be treated by a specialist or consultant physician in paediatric endocrinology; or<br>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<br>Patient must have a structural lesion that is not neoplastic; or<br>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<br>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<br>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<br>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<br>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 | Compliance with Authority Required procedures |

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| | | | | 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<br>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<br>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<br>Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies); AND<br>Patient must have hypothalamic obesity; AND<br>Patient must have a growth velocity above the 25$^{th}$ percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | Patient must be aged 3 years or older.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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<br>4. A bone age result performed within the last 12 months; AND<br>5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR<br>(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<br>(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<br>7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND<br>8. Confirmation that the patient has hypothalamic obesity; AND | |

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| | | | | 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).<br>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.<br>Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.<br>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. | |
| C12928 | P12928 | CN12928 | Somatropin | Growth retardation secondary to an intracranial lesion, or cranial irradiation<br>Continuing treatment as a reclassified patient<br>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<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; or<br>The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/$m^2$/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; AND<br>Patient must have had an intracranial lesion which is under appropriate observation and management; or<br>Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management; AND<br>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<br>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<br>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<br>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 | |

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| | | | | (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; or<br>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<br>Patient must have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment; or<br>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<br>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<br>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<br>Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more;<br>Patient must be aged 3 years or older;<br>Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology. or | |

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| | | | | Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND<br>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<br>(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<br>4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND<br>5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR<br>(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND<br>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 | |

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| | | | | 7. A bone age result performed within the last 12 months; AND<br>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).<br>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.<br>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. | |
| C12929 | P12929 | CN12929 | Somatropin | Short stature associated with chronic renal insufficiency<br>Initial treatment<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; or<br>Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ 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<br>Patient must have a current height at or below the 1$^{st}$ percentile for age and sex; or<br>Patient must have a current height above the 1$^{st}$ and at or below the 25$^{th}$ percentiles for age and sex and a growth velocity less than or equal to the 25$^{th}$ percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); or<br>Patient must have a current height above the 1$^{st}$ and at or below the 25$^{th}$ 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<br>Patient must have a current height above the 1$^{st}$ and at or below the 25$^{th}$ 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 | Compliance with Authority Required procedures |

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| | | | | Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes; AND<br>Patient must not have an active tumour or evidence of tumour growth or activity; AND<br>Patient must not have previously received treatment under the PBS S100 Growth Hormone Program; AND<br>Patient must be male and must not have a height greater than or equal to 167.7cm; or<br>Patient must be female and must not have a height greater than or equal to 155.0cm; AND<br>Patient must be male and must not have a bone age of 15.5 years or more; or<br>Patient must be female and must not have a bone age of 13.5 years or more; AND<br>Must be treated by a specialist or consultant physician in paediatric endocrinology. or<br>Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.<br>An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.<br>The 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).<br>The authority application must be in writing and must include<br>1. A completed authority prescription form; AND<br>2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND<br>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 | |

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| | | | | (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<br>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<br>5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m$^2$ ; AND<br>6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND<br>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).<br>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.<br>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. | |
| C12930 | P12930 | CN12930 | Carfilzomib | Multiple myeloma<br>Continuing treatment - twice weekly treatment regimen<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with dexamethasone; AND<br>Patient must not develop disease progression while receiving treatment with this drug for this condition; AND<br>Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or | Compliance with Authority Required procedures - Streamlined Authority Code 12930 |

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| | | | | (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<br>(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<br>(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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | |
| C12934 | P12934 | CN12934 | Carfilzomib | Multiple myeloma<br>Initial treatment - twice weekly treatment regimen<br>The condition must be confirmed by a histological diagnosis; AND<br>The treatment must be in combination with dexamethasone; AND<br>Patient must have progressive disease after at least one prior therapy; AND<br>Patient must have undergone or be ineligible for a stem cell transplant; AND<br>Patient must not have previously received this drug for this condition; AND<br>Patient must not receive more than three cycles of treatment under this restriction.<br>Progressive disease is defined as at least 1 of the following<br>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or<br>(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<br>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or | Compliance with Authority Required procedures - Streamlined Authority Code 12934 |

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| | | | | (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<br>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or<br>(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<br>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).<br>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. | |
| C12937 | P12937 | CN12937 | Enzalutamide | Castration resistant metastatic carcinoma of the prostate<br>The treatment must not be used in combination with chemotherapy; AND<br>Patient must have a WHO performance status of 2 or less; AND<br>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND<br>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<br>Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation. | Compliance with Authority Required procedures |
| C12976 | P12976 | CN12976 | Tofacitinib | Moderate to severe ulcerative colitis<br>Continuing treatment - balance of supply<br>Must be treated by a gastroenterologist (code 87); or<br>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or<br>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND<br>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND<br>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |

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| C12979 | P12979 | CN12979 | Amifampridine | Lambert-Eaton myasthenic syndrome (LEMS)<br>The condition must not be any of:<br>(i) myasthenia gravis, (ii) Guillain-Barre syndrome; AND<br>Must be treated by a prescriber type identifying as at least one of the following:<br>(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 |
| C12980 | P12980 | CN12980 | Larotrectinib | Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion<br>Continuing treatment<br>Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing; AND<br>The treatment must cease to be a PBS benefit upon radiographic progression; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.<br>Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'. | Compliance with Authority Required procedures |
| C12981 | P12981 | CN12981 | Larotrectinib | Solid tumours (of certain specified types) with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion<br>Initial treatment<br>The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence:<br>(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<br>The condition must be a mammary analogue secretory carcinoma of the salivary gland confirmed through a pathology report from an Approved Pathology Authority (of any date); or<br>The condition must be a secretory breast carcinoma confirmed through a pathology report from an Approved Pathology Authority (of any date); AND | Compliance with Authority Required procedures |

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| | | | | The condition must be metastatic disease; or<br>The condition must be both:<br>(i) locally advanced, (ii) unresectable; or<br>The condition must be both:<br>(i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND<br>Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition;<br>Patient must be at least 18 years of age.<br>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include<br>(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.<br>(b) details of the pathology report establishing the carcinoma type (salivary gland/secretory breast carcinoma) being treated, if different to the pathology report provided to substantiate the NTRK gene fusion.<br>All reports must be documented in the patient's medical records.<br>If the application is submitted through HPOS upload or mail, it must include<br>(a) a completed authority prescription form; and<br>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |
| C12982 | P12982 | 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<br>Initial treatment<br>The condition must be confirmed to be positive for a neurotrophic tropomyosin receptor kinase (NTRK) gene fusion prior to treatment initiation with this drug through a pathology report from an Approved Pathology Authority - provide the following evidence:<br>(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 | Compliance with Authority Required procedures |

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| | | | | number/code linking the pathology test result to the patient; the recency of the pathology report may be of any date; AND<br>The condition must be metastatic disease; or<br>The condition must be both:<br>(i) locally advanced, (ii) unresectable; or<br>The condition must be both:<br>(i) locally advanced, (ii) require disfiguring surgery/limb amputation to achieve complete surgical resection; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND<br>Patient must not be undergoing treatment through this Initial treatment phase listing where the patient has developed disease progression while receiving this drug for this condition;<br>Patient must be/have been under 18 years of age (i.e. prior to their 18th birthday) at treatment initiation with this drug.<br>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include<br>(a) details of the pathology report substantiating the positive NTRK gene fusion. The recency of the pathology report may be of any date.<br>All reports must be documented in the patient's medical records.<br>If the application is submitted through HPOS upload or mail, it must include<br>(a) a completed authority prescription form; and<br>(b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). | |
| C12983 | P12983 | CN12983 | Azacitidine | Myelodysplastic syndrome<br>Initial treatment<br>The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination; AND<br>The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS). or<br>The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS). | Compliance with Authority Required procedures |

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| | | | | Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations<br>a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR<br>b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR<br>c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR<br>d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR<br>e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR<br>f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.<br>Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations<br>a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR<br>b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR<br>c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR<br>d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.<br>The following information must be provided by the prescriber at the time of application<br>(a) The patient's International Prognostic Scoring System (IPSS) score<br>The following reports must be documented in the patient's medical records<br>(a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and<br>(b) full blood examination report; and | |

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| | | | | (c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).<br>No more than 3 cycles will be authorised under this restriction in a patient's lifetime. | |
| C12986 | P12986 | CN12986 | Azacitidine | Acute Myeloid Leukaemia<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have progressive disease. | Compliance with Authority Required procedures - Streamlined Authority Code 12986 |
| C12989 | P12989 | CN12989 | Trastuzumab emtansine | Metastatic (Stage IV) HER2 positive breast cancer<br>Initial treatment<br>Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; AND<br>The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; or<br>The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.<br>The following information must be provided by the prescriber at the time of application<br>(a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH).<br>(b) dates of treatment with trastuzumab and pertuzumab;<br>(c) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or | Compliance with Authority Required procedures |

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| | | | | (d) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment.<br>If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.<br>All reports must be documented in the patient's medical records.<br>Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. | |
| C12999 | P12999 | CN12999 | Zanubrutinib | Waldenstrom macroglobulinaemia<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |