



National Health (Listing of Pharmaceutical Benefits) Instrument 2024

PB 26 of 2024

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

National Health Act 1953

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This compilation is in 10 volumes

- Volume 1: sections 1-24 and Schedule 1 (Part 1: A-C)
- Volume 2: Schedule 1 (Part 1: D-I)
- Volume 3: Schedule 1 (Part 1: L-P)
- Volume 4: Schedule 1 (Part 1: Q-Z, Part 2), Schedules 2 and 3
- Volume 5: Schedule 4 (Part 1: C4076-C9993)**
- Volume 6: Schedule 4 (Part 1: C10020-C12999)
- Volume 7: Schedule 4 (Part 1: C13006-C14567)
- Volume 8: Schedule 4 (Part 1: C14568-C16349)
- Volume 9: Schedule 4 (Part 1: C16350-C17582, Part 2)
- Volume 10: Schedules 5, 6 and Endnotes

Each volume has its own contents

Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a compilation of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* that shows the text of the law as amended and in force on 1 November 2025 (the **compilation date**).

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

Uncommenced amendments

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

Application, saving and transitional provisions

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

Editorial changes

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

Presentational changes

The *Legislation Act 2003* provides for First Parliamentary Counsel to make presentational changes to a compilation. Presentational changes are applied to give a more consistent look and feel to legislation published on the Register, and enable the user to more easily navigate those documents.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. Any modifications affecting the law are accessible on the Register.

Self-repealing provisions

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

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Schedule 4—Circumstances, purposes, conditions and variations

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

Part 1—Circumstances, purposes and conditions

1 Circumstances, purposes and conditions

The following table sets out:

- (a) circumstances for circumstances codes, for the purposes of section 13 and 23; and
- (b) purposes for purposes codes, for the purposes of sections 15 and 16; and
- (c) for the purposes of section 19, information relating to how authorisation is obtained when the circumstances or conditions for writing a prescription include an authorisation requirement.

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| C4076 | P4076 | CN4076 | Atenolol | For a patient who is unable to take a solid dose form of atenolol. | |
| C4077 | P4077 | CN4077 | Granisetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| C4092 | P4092 | CN4092 | Granisetron | Nausea and vomiting The condition must be associated with radiotherapy being used to treat malignancy. | Compliance with Authority Required procedures - Streamlined Authority Code 4092 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|---------------------------|----------------------|------------------------|----------------------------|--|---|
| C4098 | P4098 | CN4098 | Apixaban Rivaroxaban | Deep vein thrombosis Initial treatment Patient must have confirmed acute symptomatic deep vein thrombosis; AND Patient must not have symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4098 |
| C4099 | P4099 | CN4099 | Apixaban Rivaroxaban | Deep vein thrombosis Continuing treatment Patient must have confirmed acute symptomatic deep vein thrombosis; AND Patient must not have symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4099 |
| C4118 | P4118 | CN4118 | Granisetron Ondansetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| C4124 | P4124 | CN4124 | Naproxen | Bone pain The condition must be due to malignant disease; AND Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent. | Compliance with Authority Required procedures - Streamlined Authority Code 4124 |
| C4132 | P4132 | CN4132 | Apixaban Rivaroxaban | Prevention of recurrent venous thromboembolism Continuing treatment Patient must have a history of venous thromboembolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4132 |
| C4139 | P4139 | CN4139 | Granisetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| C4159 | P4159 | CN4159 | Naproxen | Chronic arthropathies (including osteoarthritis) | Compliance with Authority Required |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|----------------------------|---|---|
| | | | | The condition must have an inflammatory component; AND Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent. | procedures - Streamlined Authority Code 4159 |
| C4171 | P4171 | CN4171 | Macrogol 3350 | Constipation Patient must have malignant neoplasia. | |
| C4172 | P4172 | CN4172 | Pregabalin | Neuropathic pain The condition must be refractory to treatment with other drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 4172 |
| C4173 | P4173 | CN4173 | Macrogol 3350 | Chronic constipation The condition must be inadequately controlled with first line interventions such as bulk-forming agents. | |
| C4177 | P4177 | CN4177 | Macrogol 3350 | Faecal impaction The condition must be inadequately controlled with first line interventions such as bulk-forming agents. | |
| C4179 | P4179 | CN4179 | Macrogol 3350 | Constipation Patient must be receiving palliative care. | |
| C4180 | P4180 | CN4180 | Macrogol 3350 | Constipation Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function; AND The condition must be unresponsive to other oral therapies. | |
| C4181 | P4181 | CN4181 | Ciprofloxacin Ofloxacin | Bacterial keratitis Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | Compliance with Authority Required procedures |
| C4195 | P4195 | CN4195 | Ciprofloxacin Ofloxacin | Bacterial keratitis Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| C4211 | P4211 | CN4211 | Aprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 4211 |
| C4215 | P4215 | CN4215 | Aprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND</p> <p>Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 4215 |
| C4216 | P4216 | CN4216 | Aprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND</p> <p>Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 4216 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---------------------------|---|---|
| C4223 | P4223 | CN4223 | Aprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 4223 |
| C4229 | P4229 | CN4229 | Imiquimod | <p>Superficial basal cell carcinoma</p> <p>The condition must be previously untreated; AND</p> <p>The condition must be confirmed by biopsy; AND</p> <p>Patient must have normal immune function; AND</p> <p>The condition must not be suitable for treatment with surgical excision; or</p> <p>The condition must not be suitable for treatment with cryotherapy; or</p> <p>The condition must not be suitable for treatment with curettage with diathermy; AND</p> <p>Patient must require topical drug therapy.</p> <p>The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.</p> | Compliance with Authority Required procedures |
| C4242 | P4242 | CN4242 | Vinorelbine | Locally advanced or metastatic non-small cell lung cancer | Compliance with Authority Required procedures |
| C4243 | P4243 | CN4243 | Cefalexin Trimethoprim | Prophylaxis of urinary tract infection | Compliance with Authority Required procedures - |

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|--------------------|---------------|-----------------|---|--|---|
| | | | | | Streamlined Authority Code 4243 |
| C4244 | P4244 | CN4244 | Diazepam | Chronic spasticity Patient must be under 18 years of age. | Compliance with Authority Required procedures |
| C4246 | P4246 | CN4246 | Amisulpride Aripiprazole Asenapine Brexipiprazole Cariprazine Lurasidone Olanzapine Paliperidone Quetiapine Risperidone Ziprasidone | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 4246 |
| C4253 | P4253 | CN4253 | High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate | Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet. or Patient must have a glucose transport protein defect. or Patient must have pyruvate dehydrogenase deficiency. KetoCal 3 1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. | |
| C4268 | P4268 | CN4268 | Apixaban | Pulmonary embolism | Compliance with |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | Rivaroxaban | Continuing treatment Patient must have confirmed acute symptomatic pulmonary embolism. | Authority Required procedures - Streamlined Authority Code 4268 |
| C4269 | P4269 | CN4269 | Apixaban Dabigatran etexilate Rivaroxaban | Prevention of stroke or systemic embolism Patient must have non-valvular atrial fibrillation; AND Patient must have one or more risk factors for developing stroke or systemic embolism. Risk factors for developing stroke or systemic ischaemic embolism are (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism; (ii) age 75 years or older; (iii) hypertension; (iv) diabetes mellitus; (v) heart failure and/or left ventricular ejection fraction 35% or less. | Compliance with Authority Required procedures - Streamlined Authority Code 4269 |
| C4272 | P4272 | CN4272 | Vinorelbine | Advanced breast cancer Patient must have failed standard prior therapy, which includes an anthracycline. | Compliance with Authority Required procedures |
| C4289 | P4289 | CN4289 | High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate | Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet. or Patient must have a glucose transport protein defect. or Patient must have pyruvate dehydrogenase deficiency. KetoCal 4 1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. | |
| C4295 | P4295 | CN4295 | Amino acid formula with carbohydrate without phenylalanine Amino acid formula with carbohydrate, vitamins, minerals and trace elements | Phenylketonuria | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | without phenylalanine | | |
| | | | Amino acid formula with vitamins and minerals without phenylalanine | | |
| | | | Amino acid formula with vitamins and minerals, low phenylalanine and supplemented with docosahexaenoic acid and arachidonic acid | | |
| | | | Amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine | | |
| | | | Amino acid formula without phenylalanine | | |
| | | | Glycomacropeptide and essential amino acids with vitamins and minerals | | |
| | | | Glycomacropeptide formula with amino acids and low phenylalanine | | |
| | | | Glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine | | |
| | | | Glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine | | |
| | | | Tyrosine with carbohydrate | | |
| C4302 | P4302 | CN4302 | Iron polymaltose complex | Iron deficiency anaemia Patient must be undergoing chronic haemodialysis. | Compliance with Authority Required |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | Iron sucrose | | procedures - Streamlined Authority Code 4302 |
| C4305 | P4305 | CN4305 | <p>Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids</p> <p>Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides</p> <p>Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids</p> <p>Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides</p> <p>Amino acids-synthetic, formula</p> | <p>Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae</p> <p>Initial treatment for up to 6 months</p> <p>Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist; AND</p> <p>The condition must not be isolated infant colic or reflux;</p> <p>Patient must be older than 24 months of age.</p> <p>The name of the specialist and the date of birth of the patient must be included in the authority application.</p> | Compliance with Authority Required procedures |
| C4306 | P4306 | CN4306 | Rifaximin | <p>Prevention of hepatic encephalopathy</p> <p>Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist; AND</p> <p>The treatment must be in combination with lactulose, if lactulose is tolerated; AND</p> <p>Patient must have had prior episodes of hepatic encephalopathy.</p> | Compliance with Authority Required procedures |
| C4311 | P4311 | CN4311 | <p>Amlodipine with valsartan and hydrochlorothiazide</p> <p>Olmesartan with amlodipine and hydrochlorothiazide</p> | <p>Hypertension</p> <p>The treatment must not be for the initiation of anti-hypertensive therapy; AND</p> <p>The condition must be inadequately controlled with concomitant treatment with two of the following:</p> | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic. | |
| C4312 | P4312 | CN4312 | <p>Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids</p> <p>Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides</p> <p>Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids</p> <p>Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides</p> <p>Amino acids-synthetic, formula</p> | <p>Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein</p> <p>Initial treatment for up to 6 months</p> <p>Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist; AND</p> <p>Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides);</p> <p>Patient must be up to the age of 24 months.</p> <p>The name of the specialist and the date of birth of the patient must be included in the authority application.</p> | Compliance with Authority Required procedures |
| C4313 | P4313 | CN4313 | Darunavir | <p>Human immunodeficiency virus (HIV) infection</p> <p>The treatment must be in addition to optimised background therapy; AND</p> <p>The treatment must be in combination with other antiretroviral agents; AND</p> <p>The treatment must be co-administered with 100 mg ritonavir; AND</p> <p>Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen; AND</p> <p>Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 4313 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| C4319 | P4319 | CN4319 | Ivermectin | Onchocerciasis | Compliance with Authority Required procedures - Streamlined Authority Code 4319 |
| C4323 | P4323 | CN4323 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | Cows' milk protein enteropathy Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist; AND The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula; Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application. | Compliance with Authority Required procedures |
| C4328 | P4328 | CN4328 | Ivermectin | Strongyloidiasis | Compliance with Authority Required procedures - Streamlined Authority Code 4328 |
| C4330 | P4330 | CN4330 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids Amino acid formula with fat, | Cows' milk anaphylaxis Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist; Patient must be up to the age of 24 months. | 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) |
|--------------------|---------------|-----------------|---|--|---|
| | | | carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction. The name of the specialist and the date of birth of the patient must be included in the authority application. | |
| C4337 | P4337 | CN4337 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | Cows' milk protein enteropathy Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists; AND The condition must not be isolated infant colic or reflux; AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula; Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application. | Compliance with Authority Required procedures |
| C4338 | P4338 | CN4338 | Amino acid formula supplemented with prebiotics, probiotics and long chain | Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae | Compliance with Authority Required |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | polyunsaturated fatty acids Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months; AND The condition must not be isolated infant colic or reflux; Patient must be older than 24 months of age. The name of the specialist and the date of birth of the patient must be included in the authority application. | procedures |
| C4339 | P4339 | CN4339 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist; AND Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment; Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application. | 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) |
|--------------------|---------------|-----------------|---|---|---|
| C4343 | P4343 | CN4343 | Bimatoprost with timolol Brimonidine with timolol Brinzolamide with brimonidine Brinzolamide with timolol Dorzolamide with timolol Latanoprost with timolol Travoprost with timolol | Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma. or Patient must have ocular hypertension. | |
| C4345 | P4345 | CN4345 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | Severe cows' milk protein enteropathy with failure to thrive Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists; AND The condition must not be isolated infant colic or reflux; AND Patient must have had failure to thrive prior to commencement with initial treatment; Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application. | Compliance with Authority Required procedures |
| C4351 | P4351 | CN4351 | Everolimus | Tuberous sclerosis complex (TSC) Initial treatment The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; or | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | The condition must be visceral tumours associated with TSC; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not be a candidate for curative surgical resection. | |
| C4352 | P4352 | CN4352 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | Severe cows' milk protein enteropathy with failure to thrive Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist; AND The condition must not be isolated infant colic or reflux; Patient must be up to the age of 24 months. The name of the specialist and the date of birth of the patient must be included in the authority application. | Compliance with Authority Required procedures |
| C4359 | P4359 | CN4359 | Apixaban | Prevention of venous thromboembolism Patient must be undergoing total hip replacement; AND Patient must require up to 10 days supply to complete a course of treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 4359 |
| C4361 | P4361 | CN4361 | Valsartan with hydrochlorothiazide | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist. or | |

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Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| | | | | The condition must be inadequately controlled with a thiazide diuretic. | |
| C4368 | P4368 | CN4368 | <p>Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids</p> <p>Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides</p> <p>Amino acids-synthetic, formula</p> | <p>Eosinophilic oesophagitis</p> <p>Initial treatment for up to 3 months</p> <p>Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist; AND</p> <p>Patient must require an amino acid based formula as a component of a dietary elimination program;</p> <p>Patient must be 18 years of age or less.</p> <p>Treatment with oral steroids should not be commenced during the period of initial treatment.</p> <p>Eosinophilic oesophagitis is demonstrated by the following criteria</p> <p>(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and</p> <p>(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and</p> <p>(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.</p> <p>The date of birth of the patient must be included in the authority application.</p> | Compliance with Authority Required procedures |
| C4369 | P4369 | CN4369 | Dabigatran etexilate | <p>Prevention of venous thromboembolism</p> <p>Patient must be undergoing total hip replacement; AND</p> <p>Patient must require up to 20 days supply to complete a course of treatment.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 4369 |
| C4373 | P4373 | CN4373 | <p>Amlodipine with valsartan</p> <p>Olmesartan with amlodipine</p> <p>Telmisartan with amlodipine</p> | <p>Hypertension</p> <p>The treatment must not be for the initiation of anti-hypertensive therapy; AND</p> <p>The condition must be inadequately controlled with an angiotensin II</p> | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | antagonist. or The condition must be inadequately controlled with a dihydropyridine calcium channel blocker. | |
| C4374 | P4374 | CN4374 | Candesartan with hydrochlorothiazide Eprosartan with hydrochlorothiazide Irbesartan with hydrochlorothiazide Olmesartan with hydrochlorothiazide Telmisartan with hydrochlorothiazide Valsartan with hydrochlorothiazide | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist. or The condition must be inadequately controlled with a thiazide diuretic. | |
| C4375 | P4375 | CN4375 | Perindopril with indapamide | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor. or The condition must be inadequately controlled with a thiazide-like diuretic. | |
| C4380 | P4380 | CN4380 | Budesonide with formoterol | Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; or Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; or Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy; Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 4380 |
| C4381 | P4381 | CN4381 | Apixaban | Prevention of venous thromboembolism Patient must be undergoing total knee replacement; AND | Compliance with Authority Required procedures - |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | Dabigatran etexilate | Patient must require up to 10 days of therapy. | Streamlined Authority Code 4381 |
| C4382 | P4382 | CN4382 | Apixaban Rivaroxaban | Prevention of venous thromboembolism Patient must be undergoing total knee replacement; AND Patient must require up to 15 days of therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 4382 |
| C4389 | P4389 | CN4389 | Enalapril with hydrochlorothiazide | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor. or The condition must be inadequately controlled with a thiazide diuretic. | |
| C4390 | P4390 | CN4390 | Trandolapril with verapamil | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor. or The condition must be inadequately controlled with verapamil. | |
| C4395 | P4395 | CN4395 | Fluticasone propionate with formoterol | Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 4395 |
| C4397 | P4397 | CN4397 | Budesonide with formoterol | Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; or Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; or | Compliance with Authority Required procedures - Streamlined Authority Code 4397 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist; Patient must be aged 12 years or over. | |
| C4398 | P4398 | CN4398 | Lercanidipine with enalapril Perindopril with amlodipine Ramipril with felodipine | Hypertension The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an ACE inhibitor. or The condition must be inadequately controlled with a dihydropyridine calcium channel blocker. | |
| C4402 | P4402 | CN4402 | Apixaban Dabigatran etexilate Rivaroxaban | Prevention of venous thromboembolism Patient must be undergoing total hip replacement; AND Patient must require up to 30 days supply to complete a course of treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 4402 |
| C4404 | P4404 | CN4404 | Budesonide with formoterol | Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 4404 |
| C4409 | P4409 | CN4409 | Apixaban | Prevention of venous thromboembolism Patient must be undergoing total hip replacement; AND Patient must require up to 15 days supply to complete a course of treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 4409 |
| C4414 | P4414 | CN4414 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain | Eosinophilic oesophagitis Continuing treatment Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist; AND Patient must have responded to an initial course of PBS-subsidised | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | treatment; Patient must be 18 years of age or less. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment. | |
| C4415 | P4415 | CN4415 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula | Severe intestinal malabsorption including short bowel syndrome Patient must have failed to respond to protein hydrolysate formulae. or Patient must have been receiving parenteral nutrition. | Compliance with Authority Required procedures |
| C4418 | P4418 | CN4418 | Perindopril with amlodipine | Stable coronary heart disease The treatment must not be for the initiation of therapy for coronary heart disease; AND The condition must be stabilised by treatment with perindopril and amlodipine at the same doses. | |
| C4433 | P4433 | CN4433 | Pamidronic acid | Hypercalcaemia of malignancy | Compliance with Authority Required |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| | | | | Patient must have a malignancy refractory to anti-neoplastic therapy. | procedures - Streamlined Authority Code 4433 |
| C4438 | P4438 | CN4438 | Carbohydrate, fat, vitamins, minerals and trace elements Carbohydrate, fat, vitamins, minerals and trace elements and supplemented with arachidonic acid and docosahexaenoic acid Triglycerides, long chain with glucose polymer Triglycerides, medium chain and long chain with glucose polymer | Proven inborn errors of protein metabolism Patient must be unable to meet their energy requirements with permitted food and formulae. | |
| C4454 | P4454 | CN4454 | Abacavir Atazanavir Atazanavir with cobicistat Dolutegravir Emtricitabine with tenofovir alafenamide Lamivudine Lamivudine with zidovudine Lopinavir with ritonavir Nevirapine Raltegravir Rilpivirine | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4454 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | Ritonavir Zidovudine | | |
| C4470 | P4470 | CN4470 | Bictegravir with emtricitabine with tenofovir alafenamide Emtricitabine with rilpivirine with tenofovir alafenamide Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat Tenofovir with emtricitabine and efavirenz | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 4470 |
| C4475 | P4475 | CN4475 | Doxycycline | Chronic bronchitis Patient must be aged 8 years or older. | |
| C4485 | P4485 | CN4485 | Doxycycline | Urethritis | |
| C4512 | P4512 | CN4512 | Abacavir Atazanavir Atazanavir with cobicistat Dolutegravir Emtricitabine with tenofovir alafenamide Lamivudine Lamivudine with zidovudine Lopinavir with ritonavir Nevirapine | HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4512 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | Raltegravir Rilpivirine Ritonavir Zidovudine | | |
| C4514 | P4514 | CN4514 | Doxycycline | Pelvic inflammatory disease | |
| C4516 | P4516 | CN4516 | Acidinium Glycopyrronium Umeclidinium | Chronic obstructive pulmonary disease (COPD) | |
| C4522 | P4522 | CN4522 | Bictegravir with emtricitabine with tenofovir alafenamide Emtricitabine with rilpivirine with tenofovir alafenamide Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat Tenofovir with emtricitabine and efavirenz | HIV infection Initial Patient must be antiretroviral treatment naive. | Compliance with Authority Required procedures - Streamlined Authority Code 4522 |
| C4527 | P4527 | CN4527 | Abacavir with lamivudine | HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents; Patient must be aged 12 years or older; Patient must weigh 40 kg or more. | Compliance with Authority Required procedures - Streamlined Authority Code 4527 |
| C4528 | P4528 | CN4528 | Abacavir with lamivudine | HIV infection Continuing | Compliance with Authority Required procedures - |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|----------------------------|--|---|
| | | | | Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents; Patient must be aged 12 years or older; Patient must weigh 40 kg or more. | Streamlined Authority Code 4528 |
| C4529 | P4529 | CN4529 | Doxycycline | Severe acne | |
| C4539 | P4539 | CN4539 | Doxycycline | Bronchiectasis Patient must be aged 8 years or older. | |
| C4549 | P4549 | CN4549 | Plerixafor | Mobilisation of haematopoietic stem cells The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND Patient must have lymphoma; or Patient must have multiple myeloma; AND Patient must require autologous stem cell transplantation; AND Patient must have failed previous stem cell collection. or Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection. or Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 4549 |
| C4555 | P4555 | CN4555 | Arginine with carbohydrate | Urea cycle disorders | |
| C4562 | P4562 | CN4562 | Naratriptan | Migraine attack The condition must have usually failed to respond to analgesics in the past. | Compliance with Authority Required procedures |
| C4565 | P4565 | CN4565 | Ivermectin | Crusted (Norwegian) scabies The condition must be established by clinical and/or parasitological | Compliance with Authority Required |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---------------|--|---|
| | | | | examination; AND Patient must be undergoing topical therapy for this condition; or Patient must have a contraindication to topical treatment; Patient must weigh 15 kg or over; Patient must be 5 years of age or older. | procedures - Streamlined Authority Code 4565 |
| C4566 | P4566 | CN4566 | Ivermectin | Human sarcoptic scabies The condition must be established by clinical and/or parasitological examination; AND Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; or Patient must have a contraindication to topical treatment; Patient must weigh 15 kg or over; Patient must be 5 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4566 |
| C4575 | P4575 | CN4575 | Lanreotide | Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 4575 |
| C4576 | P4576 | CN4576 | Macrogol 3350 | Constipation Patient must have malignant neoplasia. | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|---------------------------|----------------------|------------------------|--------------------|---|---|
| C4577 | P4577 | CN4577 | Macrogol 3350 | Constipation Patient must be receiving palliative care. | |
| C4580 | P4580 | CN4580 | Macrogol 3350 | Constipation Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function; AND The condition must be unresponsive to other oral therapies. | |
| C4586 | P4586 | CN4586 | Calcium | Hyperphosphataemia The condition must be associated with chronic renal failure. | Compliance with Authority Required procedures - Streamlined Authority Code 4586 |
| C4596 | P4596 | CN4596 | Macrogol 3350 | Chronic constipation The condition must be inadequately controlled with first line interventions such as bulk-forming agents. | |
| C4599 | P4599 | CN4599 | Betaine | Homocystinuria The treatment must be as adjunctive therapy to current standard care; AND The condition must be treated by or in consultation with a metabolic physician. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C4600 | P4600 | CN4600 | Erlotinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014; AND Patient must not have progressive disease; Patient must have a wild type epidermal growth factor receptor (EGFR) gene. or Patient must have an epidermal growth factor receptor (EGFR) gene of | Compliance with Authority Required procedures - Streamlined Authority Code 4600 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | unknown type. | |
| C4601 | P4601 | CN4601 | Macrogol 3350 | Faecal impaction The condition must be inadequately controlled with first line interventions such as bulk-forming agents. | |
| C4649 | P4649 | CN4649 | Eribulin | Locally advanced or metastatic breast cancer Patient must have progressive disease; AND Patient must have failed at least two prior chemotherapeutic regimens for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 4649 |
| C4651 | P4651 | CN4651 | Triglycerides - medium chain, formula | Hyperlipoproteinaemia type 1 | |
| C4652 | P4652 | CN4652 | Triglycerides - medium chain, formula | Chylous ascites | |
| C4653 | P4653 | CN4653 | Triglycerides - medium chain, formula | Chylothorax | |
| C4657 | P4657 | CN4657 | Paclitaxel, nanoparticle albumin-bound | Stage IV (metastatic) adenocarcinoma of the pancreas The treatment must be in combination with gemcitabine; AND The condition must not have been treated previously with PBS-subsidised therapy; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less. 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 4657 |
| C4659 | P4659 | CN4659 | Triglycerides - medium chain, formula | Long chain fatty acid oxidation disorders | |
| C4660 | P4660 | CN4660 | Triglycerides - medium chain, formula | Dietary management of conditions requiring a source of medium chain triglycerides Patient must have fat malabsorption due to liver disease. or Patient must have fat malabsorption due to short gut syndrome. or Patient must have fat malabsorption due to cystic fibrosis. or | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | Patient must have fat malabsorption due to gastrointestinal disorders. | |
| C4680 | P4680 | CN4680 | Escitalopram | Major depressive disorders | |
| C4681 | P4681 | CN4681 | Escitalopram | Moderate to severe social anxiety disorder (social phobia, SAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist. | |
| C4690 | P4690 | CN4690 | Escitalopram | Moderate to severe social anxiety disorder (social phobia, SAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist. | |
| C4703 | P4703 | CN4703 | Escitalopram | Moderate to severe generalised anxiety disorder (GAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared. | |
| C4704 | P4704 | CN4704 | Glycine with carbohydrate | Isovaleric acidaemia | |
| C4707 | P4707 | CN4707 | Escitalopram | Moderate to severe generalised anxiety disorder (GAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist. | |
| C4709 | P4709 | CN4709 | High fat formula with vitamins, minerals and trace elements and low in protein | Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet. or | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------------------------------|---|---|
| | | | and carbohydrate | Patient must have a glucose transport protein defect. or Patient must have pyruvate dehydrogenase deficiency. KetoCal 4 1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. | |
| C4711 | P4711 | CN4711 | Fluticasone furoate with vilanterol | Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 4711 |
| C4721 | P4721 | CN4721 | Escitalopram | Moderate to severe social anxiety disorder (social phobia, SAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared. | |
| C4731 | P4731 | CN4731 | Fluticasone furoate with vilanterol | Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; Patient must be aged 12 years or over. | Compliance with Authority Required procedures - Streamlined Authority Code 4731 |
| C4747 | P4747 | CN4747 | Escitalopram | Moderate to severe generalised anxiety disorder (GAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared. | |
| C4755 | P4755 | CN4755 | Citalopram | Major depressive disorders | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | Escitalopram Fluoxetine Fluvoxamine Paroxetine Sertraline | | |
| C4756 | P4756 | CN4756 | Escitalopram | Moderate to severe generalised anxiety disorder (GAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must have been assessed by a psychiatrist. | |
| C4757 | P4757 | CN4757 | Escitalopram | Moderate to severe social anxiety disorder (social phobia, SAD) The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria; AND Patient must not have responded to non-pharmacological therapy; AND Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared. | |
| C4785 | P4785 | CN4785 | Cetuximab | Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Initial treatment The treatment must be in combination with radiotherapy; AND Patient must be unable to tolerate cisplatin. | Compliance with Authority Required procedures - Streamlined Authority Code 4785 |
| C4788 | P4788 | CN4788 | Cetuximab | Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Continuing treatment The treatment must be in combination with radiotherapy; AND Patient must be unable to tolerate cisplatin. or | Compliance with Authority Required procedures - Streamlined Authority Code 4788 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | Patient must have a contraindication to cisplatin according to the TGA-approved Product Information. | |
| C4793 | P4793 | CN4793 | Arsenic | Acute promyelocytic leukaemia Induction and consolidation treatment The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript; AND The condition must be relapsed; AND Patient must be arsenic naive at induction. | Compliance with Authority Required procedures - Streamlined Authority Code 4793 |
| C4794 | P4794 | CN4794 | Cetuximab | Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx Initial treatment The treatment must be for the week prior to radiotherapy; AND Patient must have a contraindication to cisplatin according to the TGA-approved Product Information. | Compliance with Authority Required procedures - Streamlined Authority Code 4794 |
| C4796 | P4796 | CN4796 | Exemestane | Metastatic (Stage IV) breast cancer The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND Patient must be receiving PBS-subsidised everolimus concomitantly for this condition; Patient must not be pre-menopausal. | |
| C4812 | P4812 | CN4812 | Everolimus | Metastatic (Stage IV) breast cancer The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole; AND The treatment must be in combination with exemestane; | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | Patient must not be pre-menopausal. | |
| C4837 | P4837 | CN4837 | Everolimus | Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must not have disease progression; AND The treatment must be as monotherapy. Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures |
| C4861 | P4861 | CN4861 | Everolimus | Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Initial treatment Patient must be symptomatic (despite somatostatin analogues); or Patient must have disease progression; AND The treatment must be as monotherapy. Disease progression must be documented in the patient's medical records. Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus. Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus. | Compliance with Authority Required procedures |
| C4862 | P4862 | CN4862 | Sunitinib | Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Initial treatment Patient must be symptomatic (despite somatostatin analogues); or Patient must have disease progression; AND The treatment must be as monotherapy. Disease progression must be documented in the patient's medical records. Patients who have developed progressive disease on everolimus are not | 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) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | eligible to receive PBS-subsidised sunitinib for this condition. Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib. | |
| C4890 | P4890 | CN4890 | Goserelin | Carcinoma of the prostate The condition must be locally advanced (stage C). or The condition must be metastatic (stage D). | |
| C4892 | P4892 | CN4892 | Goserelin | Endometriosis The condition must be visually proven; AND The treatment must be for the short-term (up to 6 months). | |
| C4895 | P4895 | CN4895 | Goserelin and bicalutamide Leuprorelin and bicalutamide | Carcinoma of the prostate The condition must be metastatic (stage D); AND Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist. | |
| C4897 | P4897 | CN4897 | Temozolomide | Glioblastoma multiforme Patient must be undergoing concomitant radiotherapy. | |
| C4898 | P4898 | CN4898 | Adapalene with benzoyl peroxide | Severe acne vulgaris The treatment must be maintenance therapy. | |
| C4899 | P4899 | CN4899 | Hydrocortisone | Corticosteroid-responsive dermatoses | |
| C4902 | P4902 | CN4902 | Methadone | Chronic severe disabling pain Initial treatment, for up to 3 months Patient must be receiving palliative care; AND The condition must be unresponsive to non-opioid analgesics. | Compliance with Authority Required procedures |
| C4907 | P4907 | CN4907 | Celecoxib Meloxicam | Rheumatoid arthritis The treatment must be for symptomatic treatment. | |
| C4908 | P4908 | CN4908 | Cetuximab | Metastatic colorectal cancer | Compliance with |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------------------|--|---|
| | | | | Initial treatment Patient must have RAS wild-type metastatic colorectal cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must be previously untreated; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. | Authority Required procedures - Streamlined Authority Code 4908 |
| C4909 | P4909 | CN4909 | Adrenaline (epinephrine) | Acute allergic reaction with anaphylaxis Initial sole PBS-subsidised supply for anticipated emergency treatment Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist. or Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist. or Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician. or Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply. | Compliance with Authority Required procedures |
| C4910 | P4910 | CN4910 | Enoxaparin | Haemodialysis | |
| C4912 | P4912 | CN4912 | Cetuximab | Metastatic colorectal cancer Continuing treatment Patient must have received an initial authority prescription for this drug for first-line treatment of RAS wild-type metastatic colorectal cancer; AND Patient must not have progressive disease; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 4912 |
| C4919 | P4919 | CN4919 | Bivalirudin | Coronary artery disease | Compliance with |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | Patient must be undergoing percutaneous coronary intervention. | Authority Required procedures - Streamlined Authority Code 4919 |
| C4923 | P4923 | CN4923 | Amino acid formula with vitamins and minerals without phenylalanine and tyrosine | Tyrosinaemia | |
| C4924 | P4924 | CN4924 | Betamethasone Triamcinolone | Corticosteroid-responsive dermatoses | |
| C4925 | P4925 | CN4925 | Essential amino acids formula Essential amino acids formula with minerals and vitamin c Essential amino acids formula with vitamins and minerals | Gyrate atrophy of the choroid and retina | |
| C4930 | P4930 | CN4930 | Fluticasone propionate with salmeterol | Asthma Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; Patient must be aged 4 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4930 |
| C4934 | P4934 | CN4934 | Hydrocortisone | Corticosteroid-responsive dermatoses | |
| C4937 | P4937 | CN4937 | Eplerenone | Heart failure with a left ventricular ejection fraction of 40% or less The condition must occur within 3 to 14 days following an acute myocardial infarction; AND The treatment must be commenced within 14 days of an acute myocardial infarction. The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical | Compliance with Authority Required procedures - Streamlined Authority Code 4937 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | records when PBS-subsidised treatment is initiated | |
| C4941 | P4941 | CN4941 | Methadone | Chronic severe disabling pain Continuing treatment Patient must be receiving palliative care; AND The condition must be unresponsive to non-opioid analgesics. | Compliance with Authority Required procedures |
| C4944 | P4944 | CN4944 | Moxonidine | Hypertension Patient must be receiving concurrent antihypertensive therapy. | |
| C4947 | P4947 | CN4947 | Adrenaline (epinephrine) | Acute allergic reaction with anaphylaxis Continuing sole PBS-subsidised supply for anticipated emergency treatment Patient must have previously been issued with an authority prescription for this drug. | Compliance with Authority Required procedures |
| C4954 | P4954 | CN4954 | Amino acid formula with vitamins and minerals without valine, leucine and isoleucine | Maple syrup urine disease | |
| C4957 | P4957 | CN4957 | Betamethasone Methylprednisolone Mometasone | Corticosteroid-responsive dermatoses | |
| C4958 | P4958 | CN4958 | Essential amino acids formula Essential amino acids formula with minerals and vitamin c Essential amino acids formula with vitamins and minerals | Urea cycle disorders | |
| C4961 | P4961 | CN4961 | Adapalene with benzoyl peroxide | Severe acne vulgaris Acute treatment The treatment must in combination with an oral antibiotic. | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| C4962 | P4962 | CN4962 | Celecoxib Meloxicam | Osteoarthritis The treatment must be for symptomatic treatment. | |
| C4963 | P4963 | CN4963 | Fusidic acid | Serious staphylococcal infections The treatment must be used in combination with another antibiotic; AND The condition must be proven to be due to a staphylococcus. | |
| C4964 | P4964 | CN4964 | Amino acid formula with vitamins and minerals without phenylalanine | Phenylketonuria | |
| C4979 | P4979 | CN4979 | Ivabradine | Chronic heart failure Patient must be symptomatic with NYHA classes II or III; AND Patient must be in sinus rhythm; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; AND Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated; AND Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated. Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest. The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 4979 |
| C4980 | P4980 | CN4980 | Valganciclovir | Cytomegalovirus retinitis Patient must have HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 4980 |
| C4993 | P4993 | CN4993 | Entecavir | Chronic hepatitis B infection Patient must not have cirrhosis; AND | Compliance with Authority Required procedures - |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------|--|---|
| | | | Lamivudine | <p>Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; or</p> <p>Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; AND</p> <p>Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.</p> | Streamlined Authority Code 4993 |
| C4996 | P4996 | CN4996 | Captopril | Patients unable to take a solid dose form of an ACE inhibitor. | |
| C4997 | P4997 | CN4997 | Progesterone | <p>Assisted Reproductive Technology</p> <p>The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women; AND</p> <p>Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.</p> <p>The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 4997 |
| C4998 | P4998 | CN4998 | Clozapine | <p>Schizophrenia</p> <p>Continuing treatment</p> <p>Must be treated by a psychiatrist; or</p> <p>Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist; AND</p> <p>Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND</p> <p>Patient must have completed at least 18 weeks therapy; AND</p> <p>Patient must be on a clozapine dosage considered stable by a treating psychiatrist; AND</p> <p>The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.</p> <p>A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 4998 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| C5000 | P5000 | CN5000 | Ganciclovir | Cytomegalovirus retinitis Patient must be severely immunocompromised, including due to HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 5000 |
| C5008 | P5008 | CN5008 | Maraviroc | HIV infection Patient must be infected with CCR5-tropic HIV-1; AND The treatment must be in addition to optimised background therapy; AND The treatment must be in combination with other antiretroviral agents; AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. 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. A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible. | Compliance with Authority Required procedures - Streamlined Authority Code 5008 |
| C5009 | P5009 | CN5009 | Corifollitropin alfa | Assisted Reproductive Technology The treatment must be for controlled ovarian stimulation; AND Patient must have an antral follicle count of 20 or less; AND Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule; AND Patient must be undergoing a gonadotrophin releasing antagonist cycle. | Compliance with Authority Required procedures - Streamlined Authority Code 5009 |
| C5012 | P5012 | CN5012 | Glycomacropeptide and essential amino acids with vitamins and minerals Glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in | Phenylketonuria | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| phenylalanine | | | | | |
| C5014 | P5014 | CN5014 | Etravirine | <p>HIV infection</p> <p>The treatment must be in addition to optimised background therapy; AND</p> <p>The treatment must be in combination with other antiretroviral agents; AND</p> <p>Patient must be antiretroviral experienced; AND</p> <p>Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5014 |
| C5015 | P5015 | CN5015 | Clozapine | <p>Schizophrenia</p> <p>Initial treatment</p> <p>Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient; AND</p> <p>Patient must be non-responsive to other neuroleptic agents. or</p> <p>Patient must be intolerant of other neuroleptic agents.</p> <p>Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.</p> <p>The name of the consulting psychiatrist should be included in the patient's medical records.</p> <p>A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5015 |
| C5027 | P5027 | CN5027 | <p>Follitropin alfa</p> <p>Follitropin beta</p> <p>Follitropin delta</p> | <p>Assisted Reproductive Technology</p> <p>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5027 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------------------|---------------|-----------------|---|---|---|
| Human menopausal gonadotrophin | | | | | |
| C5036 | P5036 | CN5036 | Entecavir Lamivudine | Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5036 |
| C5037 | P5037 | CN5037 | Entecavir | Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed lamivudine; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5037 |
| C5038 | P5038 | CN5038 | Bimatoprost with timolol Brimonidine with timolol Brinzolamide with brimonidine Brinzolamide with timolol Dorzolamide with timolol Latanoprost with timolol Travoprost with timolol | Elevated intra-ocular pressure The condition must have been inadequately controlled with monotherapy; AND Patient must have open-angle glaucoma. or Patient must have ocular hypertension. | |
| C5044 | P5044 | CN5044 | Entecavir | Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed lamivudine; AND | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | <p>Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection. or</p> <p>Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.</p> | Code 5044 |
| C5045 | P5045 | CN5045 | Progesterone | <p>Assisted Reproductive Technology</p> <p>The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women; AND</p> <p>Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.</p> <p>The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5045 |
| C5046 | P5046 | CN5046 | Cetorelix Ganirelix Nafarelin Triptorelin | <p>Assisted Reproductive Technology</p> <p>The treatment must be for prevention of premature luteinisation and ovulation; AND</p> <p>Patient must be undergoing controlled ovarian stimulation; AND</p> <p>Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5046 |
| C5087 | P5087 | CN5087 | Poly-L-lactic acid | <p>Severe facial lipoatrophy</p> <p>Initial PBS-subsidised treatment</p> <p>The treatment must be for facial administration only; AND</p> <p>The condition must be caused by therapy for HIV infection.</p> <p>Accreditation following completion of injection administration training with Galderma is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.</p> | Compliance with Authority Required procedures |
| C5089 | P5089 | CN5089 | Calcitriol Sodium acid phosphate | Hypophosphataemic rickets | Compliance with Authority Required procedures - Streamlined Authority |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------------------------------|--|---|
| | | | | | Code 5089 |
| C5094 | P5094 | CN5094 | Darunavir | Human immunodeficiency virus (HIV) infection The treatment must be in addition to optimised background therapy; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must be co-administered with 100 mg ritonavir twice daily; AND Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity. | Compliance with Authority Required procedures - Streamlined Authority Code 5094 |
| C5095 | P5095 | CN5095 | Sodium acid phosphate | Familial hypophosphataemia | Compliance with Authority Required procedures - Streamlined Authority Code 5095 |
| C5098 | P5098 | CN5098 | Apixaban Rivaroxaban | Pulmonary embolism Initial treatment Patient must have confirmed acute symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 5098 |
| C5106 | P5106 | CN5106 | Mesna | Urothelial toxicity Prophylaxis or reduction of toxicity The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide. | |
| C5114 | P5114 | CN5114 | Calcitriol Sodium acid phosphate | Vitamin D-resistant rickets | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|----------------------------|---|---|
| | | | | | Code 5114 |
| C5122 | P5122 | CN5122 | Poly-L-lactic acid | Severe facial lipoatrophy Maintenance PBS-subsidised treatment The treatment must be for facial administration only; AND The condition must be caused by therapy for HIV infection. Accreditation following completion of injection administration training with Galderma is required to prescribe poly-L-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector. | Compliance with Authority Required procedures |
| C5123 | P5123 | CN5123 | Sodium acid phosphate | Hypercalcaemia | Compliance with Authority Required procedures - Streamlined Authority Code 5123 |
| C5130 | P5130 | CN5130 | Mesna | Urothelial toxicity Prophylaxis or reduction of toxicity The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide. | |
| C5135 | P5135 | CN5135 | Levonorgestrel | Idiopathic menorrhagia The treatment must be in a patient where oral treatments are ineffective. | |
| C5136 | P5136 | CN5136 | Cabergoline Quinagolide | Pathological hyperprolactinaemia Patient must be one in whom surgery is not indicated. | |
| C5137 | P5137 | CN5137 | Cabergoline Quinagolide | Pathological hyperprolactinaemia Patient must have had surgery for this condition with incomplete resolution. | |
| C5139 | P5139 | CN5139 | Thiamine | Thiamine deficiency The treatment must be for prophylaxis; Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| Code 5139 | | | | | |
| C5140 | P5140 | CN5140 | Nicotine | Nicotine dependence Patient must be an Aboriginal or a Torres Strait Islander person; The treatment must be the sole PBS-subsidised therapy for this condition. | |
| C5141 | P5141 | CN5141 | Eletriptan Rizatriptan Sumatriptan Zolmitriptan | Migraine attack The condition must have usually failed to respond to analgesics in the past. | |
| C5172 | P5172 | CN5172 | Bromocriptine Cabergoline | Prevention of the onset of lactation The treatment must occur in the puerperium; AND The treatment must be for medical reasons. | |
| C5174 | P5174 | CN5174 | Insulin detemir | Type 1 diabetes | |
| C5177 | P5177 | CN5177 | Minoxidil | Severe refractory hypertension The treatment must be initiated by a consultant physician. | |
| C5178 | P5178 | CN5178 | Botulinum toxin type A purified neurotoxin complex Clostridium botulinum type A toxin - haemagglutinin complex | Moderate to severe spasticity of the upper limb Patient must have cerebral palsy; Patient must be aged from 2 to 17 years inclusive; Must be treated by a neurologist. or Must be treated by an orthopaedic surgeon. or Must be treated by a paediatrician. or Must be treated by a rehabilitation specialist. or Must be treated by a plastic surgeon. | Compliance with Authority Required procedures - Streamlined Authority Code 5178 |
| C5214 | P5214 | CN5214 | Levonorgestrel | Contraception | |
| C5218 | P5218 | CN5218 | Pamidronic acid | Multiple myeloma | Compliance with Authority Required |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | | procedures - Streamlined Authority Code 5218 |
| C5221 | P5221 | CN5221 | Botulinum toxin type A purified neurotoxin complex | Blepharospasm or hemifacial spasm Patient must have blepharospasm; or Patient must have hemifacial spasm; AND Must be treated by a neurologist; or Must be treated by an ophthalmologist; or Must be treated by an otolaryngology head and neck surgeon; or Must be treated by a plastic surgeon; Patient must be aged 12 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 5221 |
| C5222 | P5222 | CN5222 | IncobotulinumtoxinA | Spasmodic torticollis Patient must have spasmodic torticollis; AND The treatment must be as monotherapy; or The treatment must be as adjunctive therapy to current standard care; AND Must be treated by a neurologist; or Must be treated by a plastic surgeon; or Must be treated by a rehabilitation specialist; Patient must be aged 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 5222 |
| C5226 | P5226 | CN5226 | Desmopressin | Primary nocturnal enuresis Patient must be 6 years of age or older; Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated | Compliance with Authority Required procedures - Streamlined Authority Code 5226 |
| C5251 | P5251 | CN5251 | Lutropin alfa | Stimulation of follicular development Patient must have severe LH deficiency; AND Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------|---|---|
| | | | | | Code 5251 |
| C5255 | P5255 | CN5255 | Calcitriol | Hypoparathyroidism | Compliance with Authority Required procedures - Streamlined Authority Code 5255 |
| C5266 | P5266 | CN5266 | Desmopressin | Cranial diabetes insipidus | Compliance with Authority Required procedures - Streamlined Authority Code 5266 |
| C5267 | P5267 | CN5267 | Desmopressin | Primary nocturnal enuresis Patient must be 6 years of age or older; Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated | Compliance with Authority Required procedures - Streamlined Authority Code 5267 |
| C5268 | P5268 | CN5268 | Dicloxacillin | Serious staphylococcal infection | |
| C5289 | P5289 | CN5289 | Levonorgestrel | Idiopathic menorrhagia The treatment must be in a patient where oral treatments are contraindicated. | |
| C5291 | P5291 | CN5291 | Pamidronic acid | Bone metastases The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 5291 |
| C5295 | P5295 | CN5295 | Desmopressin | Primary nocturnal enuresis Patient must be 6 years of age or older; Patient must be one in whom an enuresis alarm is contraindicated. | Compliance with Authority Required procedures - |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated | Streamlined Authority Code 5295 |
| C5296 | P5296 | CN5296 | Thyrotropin alfa | Ablation of thyroid remnant tissue Patient must have undergone a thyroidectomy; AND The treatment must be in combination with radioactive iodine; AND Patient must not have a known metastatic disease. | |
| C5297 | P5297 | CN5297 | Flucloxacillin | Serious staphylococcal infection | |
| C5298 | P5298 | CN5298 | Flucloxacillin | Serious staphylococcal infection | |
| C5323 | P5323 | CN5323 | Amino acid formula with vitamins and minerals without lysine and low in tryptophan | Proven glutaric aciduria type 1 | |
| C5324 | P5324 | CN5324 | Bisoprolol Carvedilol Metoprolol succinate Nebivolol | Moderate to severe heart failure Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated. | |
| C5325 | P5325 | CN5325 | Topiramate | Migraine The treatment must be for prophylaxis; AND Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months; AND Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; or Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker; AND Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk. or Patient must have experienced intolerance of a severity necessitating | Compliance with Authority Required procedures - Streamlined Authority Code 5325 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | permanent withdrawal during treatment with pizotifen. Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated. | |
| C5339 | P5339 | CN5339 | Rasagiline | Parkinson disease | |
| C5341 | P5341 | CN5341 | Riluzole | Amyotrophic lateral sclerosis Initial treatment The condition must be diagnosed by a neurologist; AND Patient must not have had the disease for more than 5 years; AND Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug; AND Patient must be ambulatory; or Patient must not be ambulatory, and must be able to either use upper limbs or to swallow; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure. The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application. | Compliance with Authority Required procedures |
| C5342 | P5342 | CN5342 | Desmopressin | Primary nocturnal enuresis Patient must be 6 years of age or older; Patient must be refractory to an enuresis alarm. | Compliance with Authority Required procedures - Streamlined Authority Code 5342 |
| C5357 | P5357 | CN5357 | Cabergoline Quinagolide | Pathological hyperprolactinaemia Patient must have had radiotherapy for this condition with incomplete resolution. | |
| C5359 | P5359 | CN5359 | Botulinum toxin type A purified neurotoxin complex Clostridium botulinum type A toxin - | Dynamic equinus foot deformity The condition must be due to spasticity; AND Patient must have cerebral palsy; AND | Compliance with Authority Required procedures - |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|----------------------------|--|---|
| | | | haemagglutinin complex | Patient must be ambulant; Patient must be aged from 2 to 17 years inclusive; Must be treated by a neurologist. or Must be treated by an orthopaedic surgeon. or Must be treated by a paediatrician. or Must be treated by a rehabilitation specialist. | Streamlined Authority Code 5359 |
| C5360 | P5360 | CN5360 | IncobotulinumtoxinA | Blepharospasm Patient must have blepharospasm; Patient must be aged 18 years or older; Must be treated by a neurologist. or Must be treated by an ophthalmologist. or Must be treated by an otolaryngology head and neck surgeon. or Must be treated by a plastic surgeon. | Compliance with Authority Required procedures - Streamlined Authority Code 5360 |
| C5366 | P5366 | CN5366 | Acamprosate | Alcohol dependence The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence. | Compliance with Authority Required procedures - Streamlined Authority Code 5366 |
| C5394 | P5394 | CN5394 | Carvedilol | Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002 | |
| C5398 | P5398 | CN5398 | Cabergoline Quinagolide | Pathological hyperprolactinaemia Patient must be one in whom radiotherapy is not indicated. | |
| C5401 | P5401 | CN5401 | Calcitriol | Hypocalcaemia The condition must be due to renal disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5401 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| C5402 | P5402 | CN5402 | Calcitriol | <p>Established osteoporosis</p> <p>Patient must have fracture due to minimal trauma.</p> <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5402 |
| C5405 | P5405 | CN5405 | Clostridium botulinum type A toxin - haemagglutinin complex | <p>Blepharospasm or hemifacial spasm</p> <p>Patient must have blepharospasm; or</p> <p>Patient must have hemifacial spasm;</p> <p>Patient must be aged 18 years or older;</p> <p>Must be treated by a neurologist. or</p> <p>Must be treated by an ophthalmologist. or</p> <p>Must be treated by an otolaryngology head and neck surgeon. or</p> <p>Must be treated by a plastic surgeon.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5405 |
| C5406 | P5406 | CN5406 | <p>Botulinum toxin type A purified neurotoxin complex</p> <p>Clostridium botulinum type A toxin - haemagglutinin complex</p> | <p>Spasmodic torticollis</p> <p>Patient must have spasmodic torticollis; AND</p> <p>The treatment must be as monotherapy; or</p> <p>The treatment must be as adjunctive therapy to current standard care; AND</p> <p>Must be treated by a neurologist. or</p> <p>Must be treated by a plastic surgeon. or</p> <p>Must be treated by a rehabilitation specialist.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5406 |
| C5408 | P5408 | CN5408 | Botulinum toxin type A purified neurotoxin complex | <p>Severe primary axillary hyperhidrosis</p> <p>Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; or</p> <p>Patient must be intolerant to topical aluminium chloride hexahydrate</p> | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | treatment; Patient must be aged 12 years or older; Must be treated by a dermatologist. or Must be treated by a neurologist. or Must be treated by a paediatrician. Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments. | Code 5408 |
| C5409 | P5409 | CN5409 | Botulinum toxin type A purified neurotoxin complex | Urinary incontinence The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study; AND The condition must be inadequately controlled by anti-cholinergic therapy; AND Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex; AND Patient must be willing and able to self-catheterise; AND The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment; AND Patient must have multiple sclerosis; or Patient must have a spinal cord injury; or Patient must be aged 18 years or older and have spina bifida; AND Must be treated by a urologist. or Must be treated by a urogynaecologist. | Compliance with Authority Required procedures - Streamlined Authority Code 5409 |
| C5411 | P5411 | CN5411 | Pramipexole | Primary severe restless legs syndrome Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome; AND Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole. | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---------------------------------------|---|---|
| | | | | <p>The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.</p> <p>The diagnostic criteria for Restless Legs Syndrome are</p> <p>(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and</p> <p>(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and</p> <p>(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and</p> <p>(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.</p> | |
| C5412 | P5412 | CN5412 | Desmopressin | <p>Primary nocturnal enuresis</p> <p>Patient must be 6 years of age or older;</p> <p>Patient must be refractory to an enuresis alarm.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5412 |
| C5413 | P5413 | CN5413 | Desmopressin | <p>Primary nocturnal enuresis</p> <p>Patient must be 6 years of age or older;</p> <p>Patient must be refractory to an enuresis alarm.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5413 |
| C5414 | P5414 | CN5414 | Flucloxacillin | Serious staphylococcal infection | |
| C5415 | P5415 | CN5415 | Dicloxacillin | Serious staphylococcal infection | |
| C5437 | P5437 | CN5437 | Goserelin | <p>Breast cancer</p> <p>The condition must be hormone receptor positive.</p> | |
| C5444 | P5444 | CN5444 | <p>Lansoprazole</p> <p>Omeprazole</p> | Gastro-oesophageal reflux disease | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------------------|---|---|
| | | | Pantoprazole Rabeprazole | | |
| C5446 | P5446 | CN5446 | Tobramycin | Septicaemia, suspected | |
| C5450 | P5450 | CN5450 | Anakinra | Moderate to severe cryopyrin associated periodic syndromes (CAPS) Must be treated by a rheumatologist or in consultation with a rheumatologist. or Must be treated by a clinical immunologist or in consultation with a clinical immunologist. A diagnosis of CAPS must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5450 |
| C5452 | P5452 | CN5452 | Panitumumab | Metastatic colorectal cancer Continuing treatment Patient must have received an initial authority prescription for panitumumab for first-line treatment of RAS wild-type metastatic colorectal cancer; AND Patient must not have progressive disease; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab. Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab. | Compliance with Authority Required procedures - Streamlined Authority Code 5452 |
| C5466 | P5466 | CN5466 | Magnesium | Chronic renal disease Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 5466 |
| C5470 | P5470 | CN5470 | Clindamycin | Gram-positive coccal infections | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------|--|---|
| | | | | The condition must not be able to be safely and effectively treated with a penicillin. | |
| C5472 | P5472 | CN5472 | Pimecrolimus | <p>Atopic dermatitis</p> <p>Short-term (up to 3 weeks) intermittent treatment</p> <p>Patient must be at least 3 months of age;</p> <p>The condition must be on the patient's face; or</p> <p>The condition must be on the patient's eyelid; AND</p> <p>Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy; AND</p> <p>The condition must have been initially diagnosed more than three months prior to this treatment; AND</p> <p>Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.</p> <p>Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by</p> <p>(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or</p> <p>(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or</p> <p>(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or</p> <p>(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5472 |
| C5482 | P5482 | CN5482 | Pimecrolimus | <p>Atopic dermatitis</p> <p>Patient must be at least 3 months of age;</p> <p>The condition must be on the patient's face; or</p> <p>The condition must be on the patient's eyelid; AND</p> | Compliance with Authority Required procedures - Streamlined Authority |

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Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| | | | | Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure; AND Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period. | Code 5482 |
| C5487 | P5487 | CN5487 | Clindamycin | Gram-positive coccal infections The condition must not be able to be safely and effectively treated with a penicillin. | |
| C5490 | P5490 | CN5490 | Tobramycin | Septicaemia, proven | |
| C5491 | P5491 | CN5491 | Lanthanum Sevelamer Sucroferic oxyhydroxide | Hyperphosphataemia Maintenance following initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; or The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents; AND Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5491 |
| C5498 | P5498 | CN5498 | Tobramycin | Pseudomonas aeruginosa infection Patient must have cystic fibrosis; AND The treatment must be systemic. | |
| C5506 | P5506 | CN5506 | Magnesium | Hypomagnesaemia Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 5506 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| C5509 | P5509 | CN5509 | Tiotropium | Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease Long-term maintenance treatment | |
| C5512 | P5512 | CN5512 | Lansoprazole Omeprazole Pantoprazole Rabeprazole | Scleroderma oesophagus | |
| C5519 | P5519 | CN5519 | Tobramycin | Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent | |
| C5522 | P5522 | CN5522 | Anastrozole Exemestane Letrozole Tamoxifen | Breast cancer The condition must be hormone receptor positive. | |
| C5526 | P5526 | CN5526 | Panitumumab | Metastatic colorectal cancer Initial Treatment Patient must have RAS wild-type metastatic colorectal cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must be previously untreated; AND The treatment must be in combination with first-line chemotherapy; AND The treatment must be the sole PBS-subsidised anti-EGFR antibody therapy for this condition. Patients who have progressive disease on cetuximab are not eligible to receive PBS-subsidised panitumumab. Patients who have developed intolerance to cetuximab of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab. | Compliance with Authority Required procedures - Streamlined Authority Code 5526 |

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|--------------------|---------------|-----------------|--|--|---|
| C5529 | P5529 | CN5529 | Omeprazole Pantoprazole | Zollinger-Ellison syndrome | |
| C5530 | P5530 | CN5530 | Lanthanum Sevelamer Sucroferic oxyhydroxide | Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; or The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents; AND Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5530 |
| C5532 | P5532 | CN5532 | Cyproterone | Moderate to severe androgenisation The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation; Patient must be female; Patient must not be pregnant. | Compliance with Authority Required procedures - Streamlined Authority Code 5532 |
| C5533 | P5533 | CN5533 | Amino acid formula with fat, carbohydrate without phenylalanine and tyrosine Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine Amino acid formula with vitamins and minerals without phenylalanine and tyrosine Amino acid formula with vitamins and minerals, without phenylalanine, | Tyrosinaemia | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | tyrosine and supplemented with arachidonic acid and docosahexaenoic acid Glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine Glycomacropeptide and essential amino acids with vitamins and minerals Phenylalanine with carbohydrate | | |
| C5534 | P5534 | CN5534 | Amino acid formula with fat, carbohydrate without methionine Amino acid formula with vitamins and minerals without methionine Amino acid formula with vitamins and minerals without methionine and supplemented with arachidonic acid and docosahexaenoic acid | Pyridoxine non-responsive homocystinuria | |
| C5535 | P5535 | CN5535 | Ciprofloxacin | Chronic suppurative otitis media Patient must be less than 18 years of age; Patient must have a grommet in situ. | Compliance with Authority Required procedures |
| C5540 | P5540 | CN5540 | Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain Mycobacterium bovis (Bacillus Calmette and Guerin), Tice strain | Primary and relapsing superficial urothelial carcinoma of the bladder | |
| C5541 | P5541 | CN5541 | Triglycerides - medium chain, formula | Dietary management of conditions requiring a source of medium chain triglycerides Patient must have fat malabsorption due to liver disease. or | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | Patient must have fat malabsorption due to short gut syndrome. or Patient must have fat malabsorption due to cystic fibrosis. or Patient must have fat malabsorption due to gastrointestinal disorders. | |
| C5542 | P5542 | CN5542 | Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine | Propionic acidaemia | |
| C5551 | P5551 | CN5551 | Ciprofloxacin | Chronic suppurative otitis media Patient must be less than 18 years of age; Patient must have perforation of the tympanic membrane. | Compliance with Authority Required procedures |
| C5559 | P5559 | CN5559 | Amino acid formula with vitamins and minerals without methionine | Pyridoxine non-responsive homocystinuria Patient must be an infant or a very young child. | |
| C5560 | P5560 | CN5560 | Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine | Methylmalonic acidaemia | |
| C5561 | P5561 | CN5561 | Amylopectin, modified long chain | Glycogen storage disease | |
| C5571 | P5571 | CN5571 | Amino acid formula with fat, carbohydrate without valine, leucine and isoleucine Amino acid formula without valine, leucine and isoleucine Amino acid formula with vitamins and minerals without valine, leucine and isoleucine Amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic | Maple syrup urine disease | |

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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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| | | | acid Isoleucine with carbohydrate Valine with carbohydrate | | |
| C5572 | P5572 | CN5572 | Ponatinib | <p>Acute lymphoblastic leukaemia</p> <p>Initial treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must be expressing the T315I mutation; AND</p> <p>Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor; AND</p> <p>Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).</p> <p>Failure of treatment is defined as either</p> <ol style="list-style-type: none"> 1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor; 2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor; 3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation. <p>Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.</p> <p>The authority application must be made in writing and must include</p> <ol style="list-style-type: none"> 1. a completed authority prescription form; and 2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS | Compliance with Written Authority Required procedures |

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| | | | | <p>authority application form; and</p> <p>3. a signed patient acknowledgement; and</p> <p>4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided</p> | |
| C5589 | P5589 | CN5589 | Ponatinib | <p>Acute lymphoblastic leukaemia</p> <p>Continuing treatment</p> <p>Patient must have previously been issued with an authority prescription for this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have progressive disease.</p> | Compliance with Authority Required procedures |
| C5593 | P5593 | CN5593 | Ciprofloxacin | <p>Chronic suppurative otitis media</p> <p>Patient must be an Aboriginal or a Torres Strait Islander person;</p> <p>Patient must be aged 1 month or older.</p> | Compliance with Authority Required procedures |
| C5597 | P5597 | CN5597 | <p>Mycobacterium bovis (Bacillus Calmette and Guérin (BCG)) Danish 1331 strain</p> <p>Mycobacterium bovis (Bacillus Calmette and Guérin), Tice strain</p> | Primary and relapsing superficial urothelial carcinoma of the bladder | |
| C5605 | P5605 | CN5605 | Zoledronic acid | <p>Bone metastases</p> <p>The condition must be due to breast cancer.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5605 |
| C5607 | P5607 | CN5607 | Albendazole | <p>Hydatid disease</p> <p>The treatment must be in conjunction with surgery. or</p> | Compliance with Authority Required |

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| | | | | The treatment must be used when a surgical cure cannot be achieved. or The treatment must be used when surgery cannot be used. | procedures - Streamlined Authority Code 5607 |
| C5609 | P5609 | CN5609 | Atovaquone | Mild to moderate Pneumocystis carinii pneumonia Patient must be an adult; Patient must be intolerant of trimethoprim/sulfamethoxazole therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5609 |
| C5611 | P5611 | CN5611 | Quetiapine | Acute mania The condition must be associated with bipolar I disorder; AND The treatment must be as monotherapy; AND The treatment must be limited to up to 6 months per episode. | Compliance with Authority Required procedures - Streamlined Authority Code 5611 |
| C5613 | P5613 | CN5613 | Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Constipation Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult. | |
| C5614 | P5614 | CN5614 | Ciprofloxacin | Bone or joint infection The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials. or The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials. | Compliance with Authority Required procedures |
| C5615 | P5615 | CN5615 | Ciprofloxacin | Prostatitis The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials. or The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials. | Compliance with Authority Required procedures |
| C5618 | P5618 | CN5618 | Ondansetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy | |

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| | | | | administration. | |
| C5633 | P5633 | CN5633 | Quinine | Malaria | Compliance with Authority Required procedures - Streamlined Authority Code 5633 |
| C5634 | P5634 | CN5634 | Dornase alfa | <p>Cystic fibrosis</p> <p>Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; or</p> <p>Patient must have significant bronchiectasis on chest high resolution computed tomography scan; or</p> <p>Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or</p> <p>Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy;</p> <p>Patient must be less than 5 years of age.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5634 |
| C5635 | P5635 | CN5635 | Dornase alfa | <p>Cystic fibrosis</p> <p>Continuing treatment</p> <p>Patient must have initiated treatment with dornase alfa at an age of less than</p> | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | 5 years; AND Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit; Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. | Code 5635 |
| C5636 | P5636 | CN5636 | Vancomycin | Antibiotic associated pseudomembranous colitis The condition must be due to Clostridium difficile; AND Patient must have an intolerance to metronidazole. | Compliance with Authority Required procedures |
| C5637 | P5637 | CN5637 | Azithromycin | Trachoma | |
| C5638 | P5638 | CN5638 | Clarithromycin | Bordetella pertussis | |
| C5640 | P5640 | CN5640 | Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Constipation Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function. | |
| C5648 | P5648 | CN5648 | Methotrexate | Patients requiring doses greater than 20 mg per week | |
| C5649 | P5649 | CN5649 | Medroxyprogesterone | Endometrial cancer | |
| C5650 | P5650 | CN5650 | Desvenlafaxine Duloxetine Mirtazapine Moclobemide Reboxetine Venlafaxine | Major depressive disorders | |

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| C5660 | P5660 | CN5660 | Vancomycin | Antibiotic associated pseudomembranous colitis The condition must be due to Clostridium difficile; AND The condition must be unresponsive to metronidazole. | Compliance with Authority Required procedures |
| C5663 | P5663 | CN5663 | Clarithromycin | Atypical mycobacterial infections | |
| C5666 | P5666 | CN5666 | Ciprofloxacin | Gonorrhoea | Compliance with Authority Required procedures |
| C5672 | P5672 | CN5672 | Benzylamine | Mucositis The condition must be radiation induced. | |
| C5680 | P5680 | CN5680 | Albendazole | Tapeworm infestation | Compliance with Authority Required procedures - Streamlined Authority Code 5680 |
| C5685 | P5685 | CN5685 | Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Anorectal congenital abnormalities | |
| C5686 | P5686 | CN5686 | Palonosetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| C5687 | P5687 | CN5687 | Ciprofloxacin | Respiratory tract infection The condition must be proven or suspected to be caused by Pseudomonas aeruginosa; AND Patient must be severely immunocompromised. | Compliance with Authority Required procedures |
| C5688 | P5688 | CN5688 | Ciprofloxacin | Infection The condition must be proven to be due to Pseudomonas aeruginosa | Compliance with Authority Required |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------------------|---|---|
| | | | | resistant to all other oral antimicrobials. or The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials. | procedures |
| C5689 | P5689 | CN5689 | Ciprofloxacin | Epididymo-orchitis The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials. or The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials. | Compliance with Authority Required procedures |
| C5697 | P5697 | CN5697 | Phenoxymethylpenicillin | Recurrent streptococcal infections (including rheumatic fever) The treatment must be for prophylaxis. | |
| C5701 | P5701 | CN5701 | Metronidazole | Anaerobic infections | |
| C5702 | P5702 | CN5702 | Metronidazole | Anaerobic infections | |
| C5703 | P5703 | CN5703 | Zoledronic acid | Bone metastases The condition must be due to castration-resistant prostate cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 5703 |
| C5704 | P5704 | CN5704 | Zoledronic acid | Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5704 |
| C5710 | P5710 | CN5710 | Zoledronic acid | Symptomatic Paget disease of bone Only 1 treatment each year per patient will be PBS-subsidised | Compliance with Authority Required procedures - Streamlined Authority Code 5710 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| C5712 | P5712 | CN5712 | Albendazole | Strongyloidiasis | Compliance with Authority Required procedures - Streamlined Authority Code 5712 |
| C5716 | P5716 | CN5716 | Vancomycin | Endophthalmitis | |
| C5717 | P5717 | CN5717 | Vancomycin | Endocarditis The treatment must be for prophylaxis; AND Patient must be hypersensitive to penicillin. | |
| C5718 | P5718 | CN5718 | Azithromycin | Urethritis The condition must be uncomplicated and due to Chlamydia trachomatis. | |
| C5719 | P5719 | CN5719 | Asenapine | Bipolar I disorder The treatment must be maintenance therapy; AND The treatment must be as monotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5719 |
| C5720 | P5720 | CN5720 | Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Constipation Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility. | |
| C5721 | P5721 | CN5721 | Ondansetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| C5722 | P5722 | CN5722 | Ciprofloxacin | Bacterial gastroenteritis Patient must be severely immunocompromised. | 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) |
|--------------------|---------------|-----------------|---------------------------|--|---|
| C5729 | P5729 | CN5729 | Bicalutamide Flutamide | Metastatic (stage D) carcinoma of the prostate The treatment must be in combination with GnRH (LH-RH) analogue therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5729 |
| C5732 | P5732 | CN5732 | Benzydamine | Mucositis The condition must be radiation induced. | |
| C5735 | P5735 | CN5735 | Zoledronic acid | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 5735 |
| C5740 | P5740 | CN5740 | Dornase alfa | Cystic fibrosis Patient must be 5 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly | Compliance with Authority Required procedures - Streamlined Authority Code 5740 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------|---|---|
| | | | | intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | |
| C5742 | P5742 | CN5742 | Ziprasidone | Acute mania or mixed episodes The condition must be associated with bipolar I disorder; AND The treatment must be as monotherapy; AND The treatment must be limited to up to 6 months per episode. | Compliance with Authority Required procedures - Streamlined Authority Code 5742 |
| C5743 | P5743 | CN5743 | Ondansetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| C5744 | P5744 | CN5744 | Norfloxacin | Acute bacterial enterocolitis | Compliance with Authority Required procedures |
| C5746 | P5746 | CN5746 | Ticagrelor | Acute coronary syndrome (myocardial infarction or unstable angina) The treatment must be in combination with aspirin. | Compliance with Authority Required procedures - Streamlined Authority Code 5746 |
| C5769 | P5769 | CN5769 | Vancomycin | Infection The treatment must be initiated in a hospital; AND The condition must be one in which vancomycin is an appropriate antibiotic. | |
| C5772 | P5772 | CN5772 | Azithromycin | Cervicitis The condition must be uncomplicated and due to Chlamydia trachomatis. | |
| C5773 | P5773 | CN5773 | Asenapine | Acute mania or mixed episodes The condition must be associated with bipolar I disorder; AND The treatment must be limited to up to 6 months per episode. | Compliance with Authority Required procedures - Streamlined Authority |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| Code 5773 | | | | | |
| C5775 | P5775 | CN5775 | Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Constipation Patient must be receiving palliative care. | |
| C5776 | P5776 | CN5776 | Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Terminal malignant neoplasia | |
| C5778 | P5778 | CN5778 | Ondansetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| C5780 | P5780 | CN5780 | Ciprofloxacin | Perichondritis of the pinna The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials. or The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials. | Compliance with Authority Required procedures |
| C5781 | P5781 | CN5781 | Fondaparinux | Prevention of venous thromboembolism Patient must be undergoing major hip surgery. | Compliance with Authority Required procedures - Streamlined Authority Code 5781 |
| C5791 | P5791 | CN5791 | Medroxyprogesterone | Breast cancer The condition must be hormone receptor positive. | |
| C5797 | P5797 | CN5797 | Albendazole | Hookworm infestation | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | | Code 5797 |
| C5801 | P5801 | CN5801 | Vancomycin | Endocarditis The treatment must be for prophylaxis; AND Patient must be hypersensitive to penicillin. | |
| C5804 | P5804 | CN5804 | Bisacodyl Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Megacolon | |
| C5805 | P5805 | CN5805 | Palonosetron | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. | |
| C5806 | P5806 | CN5806 | Norfloxacin | Complicated urinary tract infection | Compliance with Authority Required procedures |
| C5808 | P5808 | CN5808 | Fondaparinux | Prevention of venous thromboembolism Patient must be undergoing total knee replacement. | Compliance with Authority Required procedures - Streamlined Authority Code 5808 |
| C5817 | P5817 | CN5817 | Albendazole | Whipworm infestation Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 5817 |
| C5819 | P5819 | CN5819 | Bisacodyl | Constipation Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult; | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|------------------------------------|---|---|
| | | | | Patient must identify as Aboriginal or Torres Strait Islander. | |
| C5823 | P5823 | CN5823 | Bisacodyl | Anorectal congenital abnormalities Patient must identify as Aboriginal or Torres Strait Islander. | |
| C5824 | P5824 | CN5824 | Folic acid | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| C5832 | P5832 | CN5832 | Amoxicillin with clavulanic acid | Infections where resistance to amoxicillin is proven | |
| C5833 | P5833 | CN5833 | Amoxicillin with clavulanic acid | Infection where resistance to amoxicillin is suspected | |
| C5835 | P5835 | CN5835 | Chloramphenicol Paracetamol | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| C5843 | P5843 | CN5843 | Amoxicillin | Chronic bronchitis Patient must have acute exacerbations of the condition. | |
| C5846 | P5846 | CN5846 | Paracetamol | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| C5849 | P5849 | CN5849 | Naratriptan | Migraine attack The condition must have usually failed to respond to analgesics in the past; AND Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance. | Compliance with Authority Required procedures |
| C5850 | P5850 | CN5850 | Naratriptan | Migraine attack The condition must have usually failed to respond to analgesics in the past; AND Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences. | Compliance with Authority Required procedures |
| C5851 | P5851 | CN5851 | Bisacodyl | Terminal malignant neoplasia Patient must identify as Aboriginal or Torres Strait Islander. | |
| C5852 | P5852 | CN5852 | Glucose and ketone indicator-urine | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|---------------------------|----------------------|------------------------|--------------------------|---|---|
| C5855 | P5855 | CN5855 | Ceftriaxone | Gonorrhoea | |
| C5859 | P5859 | CN5859 | Naratriptan | Migraine attack The condition must have usually failed to respond to analgesics in the past; AND Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs. | Compliance with Authority Required procedures |
| C5860 | P5860 | CN5860 | Naratriptan | Migraine attack The condition must have usually failed to respond to analgesics in the past; AND Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs. | Compliance with Authority Required procedures |
| C5863 | P5863 | CN5863 | Amoxicillin | Infection suspected or proven to be due to a susceptible organism The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable. | Compliance with Authority Required procedures |
| C5865 | P5865 | CN5865 | Paracetamol | Chronic arthropathies Patient must identify as Aboriginal or Torres Strait Islander. | |
| C5866 | P5866 | CN5866 | Bisacodyl | Megacolon Patient must identify as Aboriginal or Torres Strait Islander. | |
| C5867 | P5867 | CN5867 | Cefazolin | Cellulitis | |
| C5869 | P5869 | CN5869 | Olanzapine Quetiapine | Bipolar I disorder The treatment must be maintenance therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5869 |
| C5879 | P5879 | CN5879 | Bisacodyl | Constipation Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility; | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|----------------------------------|---|---|
| | | | | Patient must identify as Aboriginal or Torres Strait Islander. | |
| C5883 | P5883 | CN5883 | Cefazolin | Cellulitis | |
| C5884 | P5884 | CN5884 | Aspirin | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| C5885 | P5885 | CN5885 | Paracetamol | Chronic arthropathies Patient must identify as Aboriginal or Torres Strait Islander. | |
| C5887 | P5887 | CN5887 | Naratriptan | Migraine attack The condition must have usually failed to respond to analgesics in the past; AND Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs. | Compliance with Authority Required procedures |
| C5889 | P5889 | CN5889 | Electrolyte replacement, oral | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| C5893 | P5893 | CN5893 | Amoxicillin with clavulanic acid | Infection where resistance to amoxicillin is suspected | |
| C5894 | P5894 | CN5894 | Amoxicillin with clavulanic acid | Infections where resistance to amoxicillin is proven | |
| C5901 | P5901 | CN5901 | Octreotide | Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 5901 |
| C5906 | P5906 | CN5906 | Octreotide | Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections; AND The treatment must cease if there is failure to produce a clinically significant | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Code 5906 |
| C5907 | P5907 | CN5907 | Risperidone | Acute mania The condition must be associated with bipolar I disorder; AND The treatment must be as adjunctive therapy to mood stabilisers; AND The treatment must be limited to up to 6 months per episode. | Compliance with Authority Required procedures - Streamlined Authority Code 5907 |
| C5912 | P5912 | CN5912 | Risperidone | Bipolar I disorder The condition must be refractory to treatment; AND The treatment must be in combination with lithium or sodium valproate; AND The treatment must be maintenance therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5912 |
| C5914 | P5914 | CN5914 | Thalidomide | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 5914 |
| C5936 | P5936 | CN5936 | Aciclovir | Initial moderate to severe genital herpes Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5936 |
| C5937 | P5937 | CN5937 | Famciclovir | Recurrent moderate to severe genital herpes Episodic treatment Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable | Compliance with Authority Required procedures - Streamlined Authority |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | but need not delay treatment. | Code 5937 |
| C5938 | P5938 | CN5938 | Folinic acid | Megaloblastic anaemias The condition must be a result of folic acid deficiency from the use of folic acid antagonists. | |
| C5940 | P5940 | CN5940 | Valaciclovir | Recurrent moderate to severe genital herpes Suppressive therapy Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5940 |
| C5941 | P5941 | CN5941 | Nitrazepam Temazepam | Insomnia Patient must be receiving this drug for the management of insomnia; AND Patient must be receiving long-term nursing care; AND Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult; AND Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
| C5942 | P5942 | CN5942 | Aciclovir | Recurrent moderate to severe genital herpes Episodic treatment or suppressive therapy Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5942 |
| C5943 | P5943 | CN5943 | Famciclovir | Herpes zoster Patient must be immunocompromised; AND The treatment must be administered within 72 hours of the onset of the rash. | Compliance with Authority Required procedures - Streamlined Authority Code 5943 |
| C5945 | P5945 | CN5945 | Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain | Eosinophilic oesophagitis Initial treatment for up to 3 months Must be treated by a clinical immunologist, suitably qualified allergist or | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| | | | triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides | gastroenterologist; AND Patient must require an amino acid based formula as a component of a dietary elimination program; Patient must be 18 years of age or less. Treatment with oral steroids should not be commenced during the period of initial treatment. Eosinophilic oesophagitis is demonstrated by the following criteria (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The date of birth of the patient must be included in the authority application. | |
| C5947 | P5947 | CN5947 | Famciclovir | Recurrent moderate to severe oral or labial herpes Episodic treatment Patient must have HIV infection; AND Patient must have a CD4 cell count of less than 500 million per litre. Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5947 |
| C5948 | P5948 | CN5948 | Famciclovir | Recurrent moderate to severe oral or labial herpes Suppressive therapy Patient must have HIV infection; AND Patient must have CD4 cell counts of less than 150 million per litre. Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5948 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------------------|---|---|
| C5949 | P5949 | CN5949 | Famciclovir | Recurrent moderate to severe oral or labial herpes Suppressive therapy Patient must have HIV infection; AND Patient must present with other opportunistic infections or AIDS defining tumours. Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5949 |
| C5950 | P5950 | CN5950 | Nitrazepam Temazepam | Insomnia Patient must be receiving this drug for the management of insomnia; AND Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility; AND Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
| C5951 | P5951 | CN5951 | Famciclovir | Herpes zoster The treatment must be administered within 72 hours of the onset of the rash. | Compliance with Authority Required procedures - Streamlined Authority Code 5951 |
| C5954 | P5954 | CN5954 | Famciclovir | Recurrent moderate to severe genital herpes Episodic treatment or suppressive therapy Patient must be immunocompromised. Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5954 |
| C5959 | P5959 | CN5959 | Aciclovir | Herpes zoster ophthalmicus | Compliance with Authority Required procedures - Streamlined Authority Code 5959 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|---------------------------|----------------------|------------------------|-----------------------------|---|---|
| C5960 | P5960 | CN5960 | Valaciclovir | Initial moderate to severe genital herpes Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5960 |
| C5961 | P5961 | CN5961 | Valaciclovir | Recurrent moderate to severe genital herpes Episodic treatment Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 5961 |
| C5962 | P5962 | CN5962 | Valaciclovir | Herpes zoster The treatment must be administered within 72 hours of the onset of the rash. | Compliance with Authority Required procedures - Streamlined Authority Code 5962 |
| C5964 | P5964 | CN5964 | Aciclovir | Herpes simplex keratitis | |
| C5965 | P5965 | CN5965 | Aciclovir | Herpes simplex keratitis | |
| C5967 | P5967 | CN5967 | Aciclovir | Herpes zoster The treatment must be administered within 72 hours of the onset of the rash. | Compliance with Authority Required procedures - Streamlined Authority Code 5967 |
| C5968 | P5968 | CN5968 | Valaciclovir | Herpes zoster ophthalmicus | Compliance with Authority Required procedures - Streamlined Authority Code 5968 |
| C5969 | P5969 | CN5969 | Sofosbuvir with velpatasvir | Chronic hepatitis C infection | Compliance with |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | <p>Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND</p> <p>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</p> <p>The treatment must be limited to a maximum duration of 12 weeks.</p> | Authority Required procedures |
| C5970 | P5970 | CN5970 | <p>Amino acid formula with fat, carbohydrate without phenylalanine</p> <p>Amino acid formula with fat, carbohydrate, vitamins and minerals without phenylalanine</p> <p>Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine</p> <p>Protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid</p> | Phenylketonuria | |
| C5971 | P5971 | CN5971 | Famciclovir | <p>Recurrent moderate to severe genital herpes</p> <p>Suppressive therapy</p> <p>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 5971 |
| C5973 | P5973 | CN5973 | Folinic acid | <p>Megaloblastic anaemias</p> <p>The condition must be a result of folic acid deficiency from the use of folic acid antagonists.</p> | |
| C5974 | P5974 | CN5974 | Amino acid formula with fat, carbohydrate, vitamins, minerals, trace | Eosinophilic oesophagitis | Compliance with Authority Required |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides | Continuing treatment Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist; AND Patient must have responded to an initial course of PBS-subsidised treatment; Patient must be 18 years of age or less. Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment. | procedures |
| C5975 | P5975 | CN5975 | Valaciclovir | Cytomegalovirus infection and disease Prophylaxis Patient must have undergone a renal transplant; AND Patient must be at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 5975 |
| C5981 | P5981 | CN5981 | Atovaquone with proguanil | Confirmed or suspected Plasmodium falciparum malaria Patient must be aged 3 years or older; The treatment must be used where quinine containing regimens are inappropriate. | |
| C5984 | P5984 | CN5984 | Citrulline | Urea cycle disorders The treatment must be for preventing low plasma arginine levels. or The treatment must be for preventing low citrulline levels. | |
| C5986 | P5986 | CN5986 | Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine | Propionic acidaemia | |
| C5989 | P5989 | CN5989 | Fluconazole | Oesophageal candidiasis Patient must be immunosuppressed. | 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) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | | Streamlined Authority Code 5989 |
| C5995 | P5995 | CN5995 | Minocycline | Severe acne The condition must not be responding to other tetracyclines. | |
| C5997 | P5997 | CN5997 | Arsenic | Acute promyelocytic leukaemia The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript. | Compliance with Authority Required procedures - Streamlined Authority Code 5997 |
| C5999 | P5999 | CN5999 | Artemether with lumefantrine | Confirmed or suspected Plasmodium falciparum malaria | |
| C6007 | P6007 | CN6007 | Amino acid formula with vitamins and minerals without lysine and low in tryptophan | Proven glutaric aciduria type 1 | |
| C6013 | P6013 | CN6013 | Dabrafenib Encorafenib Vemurafenib | Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 6013 |
| C6018 | P6018 | CN6018 | Arsenic | Acute promyelocytic leukaemia Induction and consolidation treatment The condition must be characterised by the presence of the t(15:17) translocation or PML/RAR-alpha fusion gene transcript. | Compliance with Authority Required procedures - Streamlined Authority Code 6018 |
| C6023 | P6023 | CN6023 | Fluconazole | Oropharyngeal candidiasis Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 6023 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

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|--------------------|---------------|-----------------|-------------|--|---|
| C6026 | P6026 | CN6026 | Fentanyl | Breakthrough pain Initial treatment for dose titration Patient must have cancer; AND Patient must have pain directly attributable to cancer; AND Patient must be assessed as receiving adequate management of their persistent pain with opioids; AND Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; or The treatment must be used as short acting opioids are considered clinically inappropriate; or Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain; AND Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| C6027 | P6027 | CN6027 | Fentanyl | Breakthrough pain Continuing treatment Patient must have cancer; AND Patient must have pain directly attributable to cancer; AND Patient must be assessed as receiving adequate management of their persistent pain with opioids; AND Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; or The treatment must be used as short acting opioids are considered clinically inappropriate; or Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain; AND Patient must be undergoing palliative care. | Compliance with Authority Required procedures |
| C6030 | P6030 | CN6030 | Fluconazole | Oropharyngeal candidiasis The treatment must be for prophylaxis; 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) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | Patient must be immunosuppressed. | Streamlined Authority Code 6030 |
| C6031 | P6031 | CN6031 | Fluconazole | Oropharyngeal candidiasis Patient must be immunosuppressed; AND Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6031 |
| C6032 | P6032 | CN6032 | Fluconazole | Oropharyngeal candidiasis The treatment must be for prophylaxis; AND Patient must be immunosuppressed; AND Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6032 |
| C6038 | P6038 | CN6038 | Amino acid formula with vitamins and minerals without methionine | Pyridoxine non-responsive homocystinuria | |
| C6046 | P6046 | CN6046 | Fluconazole | Oesophageal candidiasis Patient must be immunosuppressed; AND Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6046 |
| C6055 | P6055 | CN6055 | Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine | Methylmalonic acidaemia | |
| C6056 | P6056 | CN6056 | Carmustine | Glioblastoma multiforme The condition must be suspected or confirmed at the time of initial surgery. | |
| C6080 | P6080 | CN6080 | Prednisolone with phenylephrine | Corneal grafts | |
| C6084 | P6084 | CN6084 | Metoclopramide | Nausea or gastric stasis Patient must be receiving palliative care. | Compliance with Authority Required procedures - |

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|--------------------|---------------|-----------------|---|--|---|
| | | | | | Streamlined Authority Code 6084 |
| C6087 | P6087 | CN6087 | Prednisolone with phenylephrine | Uveitis | |
| C6101 | P6101 | CN6101 | Prednisolone with phenylephrine | Uveitis | |
| C6106 | P6106 | CN6106 | Paclitaxel, nanoparticle albumin-bound | Metastatic breast cancer | Compliance with Authority Required procedures - Streamlined Authority Code 6106 |
| C6118 | P6118 | CN6118 | Esomeprazole and clarithromycin and amoxicillin | Eradication of Helicobacter pylori The condition must be associated with peptic ulcer disease. | |
| C6119 | P6119 | CN6119 | Paclitaxel, nanoparticle albumin-bound | HER2 positive breast cancer | Compliance with Authority Required procedures - Streamlined Authority Code 6119 |
| C6133 | P6133 | CN6133 | Fusidic acid | Osteomyelitis The condition must be methicillin-resistant staphylococcal aureus (MRSA); AND The treatment must be used in combination with other anti-staphylococcal antibiotics. | Compliance with Authority Required procedures - Streamlined Authority Code 6133 |
| C6134 | P6134 | CN6134 | Triglycerides, medium chain | Chylothorax | Compliance with Authority Required procedures - Streamlined Authority Code 6134 |
| C6135 | P6135 | CN6135 | Triglycerides, medium chain | Cerebrospinal fluid glucose transporter defect | Compliance with |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| | | | | Patient must require a ketogenic diet. | Authority Required procedures - Streamlined Authority Code 6135 |
| C6137 | P6137 | CN6137 | Protein hydrolysate formula with medium chain triglycerides | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Initial treatment for up to 6 months Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist; Patient must be up to the age of 24 months. The name of the specialist must be documented in the patient's medical records | Compliance with Authority Required procedures - Streamlined Authority Code 6137 |
| C6138 | P6138 | CN6138 | Protein hydrolysate formula with medium chain triglycerides | Severe intestinal malabsorption including short bowel syndrome | Compliance with Authority Required procedures - Streamlined Authority Code 6138 |
| C6139 | P6139 | CN6139 | Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Constipation Patient must be receiving palliative care. | |
| C6141 | P6141 | CN6141 | Arachidonic acid and docosahexaenoic acid with carbohydrate | Peroxisomal biogenesis disorders | |
| C6146 | P6146 | CN6146 | Triglycerides, medium chain | Long chain fatty acid oxidation disorders | Compliance with Authority Required procedures - Streamlined Authority Code 6146 |

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|---------------------------|----------------------|------------------------|---|--|---|
| C6148 | P6148 | CN6148 | Protein hydrolysate formula with medium chain triglycerides | Severe diarrhoea of greater than 2 weeks duration Patient must be aged less than 4 months. | Compliance with Authority Required procedures - Streamlined Authority Code 6148 |
| C6149 | P6149 | CN6149 | Ibuprofen Indometacin Naproxen | Severe pain Patient must be receiving palliative care. | |
| C6150 | P6150 | CN6150 | Naproxen | Severe pain Patient must be undergoing palliative care; AND Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent. | |
| C6152 | P6152 | CN6152 | Vitamins, minerals and trace elements with carbohydrate | Dietary management of conditions requiring a highly restrictive therapeutic diet Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet; AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations; Patient must be an infant or a child. | |
| C6155 | P6155 | CN6155 | Triglycerides, medium chain | Intractable childhood epilepsy Patient must require a ketogenic diet. | Compliance with Authority Required procedures - Streamlined Authority Code 6155 |
| C6157 | P6157 | CN6157 | Protein hydrolysate formula with medium chain triglycerides | Chronic liver failure with fat malabsorption | Compliance with Authority Required procedures - Streamlined Authority |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | | Code 6157 |
| C6158 | P6158 | CN6158 | Protein hydrolysate formula with medium chain triglycerides | Enterokinase deficiency | Compliance with Authority Required procedures - Streamlined Authority Code 6158 |
| C6159 | P6159 | CN6159 | Vitamins, minerals and trace elements with carbohydrate | Dietary management of conditions requiring a highly restrictive therapeutic diet Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet; AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations; Patient must be aged 3 years or older. | |
| C6160 | P6160 | CN6160 | Erythromycin | Severe acne The condition must be one in which tetracycline therapy is inappropriate. | Compliance with Authority Required procedures - Streamlined Authority Code 6160 |
| C6163 | P6163 | CN6163 | Trimethoprim | Prostatitis | |
| C6164 | P6164 | CN6164 | Triglycerides, medium chain | Fat malabsorption The condition must be due to liver disease. or The condition must be due to short gut syndrome. or The condition must be due to cystic fibrosis. or The condition must be due to gastrointestinal disorders. | Compliance with Authority Required procedures - Streamlined Authority Code 6164 |
| C6166 | P6166 | CN6166 | Protein hydrolysate formula with medium chain triglycerides | Proven fat malabsorption | Compliance with Authority Required procedures - Streamlined Authority |

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|--------------------|---------------|-----------------|--|---|---|
| | | | | | Code 6166 |
| C6167 | P6167 | CN6167 | Paracetamol | Analgesia or fever Patient must be receiving palliative care; AND Patient must be intolerant to alternative therapy. | |
| C6168 | P6168 | CN6168 | Morphine | Severe disabling pain Patient must be receiving palliative care; AND The condition must be unresponsive to non-opioid analgesics. | Compliance with Authority Required procedures |
| C6170 | P6170 | CN6170 | Macrogol 3350 | Constipation Patient must be receiving palliative care. | Compliance with Authority Required procedures - Streamlined Authority Code 6170 |
| C6171 | P6171 | CN6171 | Macrogol 3350 | Constipation Patient must be receiving palliative care. | Compliance with Authority Required procedures - Streamlined Authority Code 6171 |
| C6172 | P6172 | CN6172 | Carbomer Carmellose Hyaluronic acid Hypromellose Paraffin Perfluorohexyloctane Polyethylene glycol 400 with propylene glycol | Severe dry eye syndrome Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 6172 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| Soy lecithin | | | | | |
| C6174 | P6174 | CN6174 | Protein hydrolysate formula with medium chain triglycerides | <p>Cows' milk protein enteropathy and intolerance to soy protein</p> <p>Initial treatment</p> <p>Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist; AND</p> <p>The condition must not be isolated infant colic or reflux; AND</p> <p>Patient must have failed to respond to a strict soy-based cows' milk protein free diet;</p> <p>Patient must be up to the age of 24 months.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6174 |
| C6175 | P6175 | CN6175 | Nitrazepam Temazepam | <p>Insomnia</p> <p>Patient must be receiving palliative care.</p> | Compliance with Authority Required procedures |
| C6176 | P6176 | CN6176 | Diazepam Oxazepam | <p>Anxiety</p> <p>Patient must be receiving palliative care.</p> | Compliance with Authority Required procedures |
| C6180 | P6180 | CN6180 | Methylnaltrexone | <p>Opioid-induced constipation</p> <p>The treatment must be in combination with oral laxatives; AND</p> <p>Patient must be receiving palliative care; AND</p> <p>Patient must have failed to respond to laxatives.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6180 |
| C6181 | P6181 | CN6181 | Triglycerides, medium chain | Chylous ascites | Compliance with Authority Required procedures - Streamlined Authority Code 6181 |

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|---------------------------|----------------------|------------------------|--|--|---|
| C6182 | P6182 | CN6182 | Protein hydrolysate formula with medium chain triglycerides | Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Continuing treatment Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist; Patient must be up to the age of 24 months. The name of the specialist must be documented in the patient's medical records | Compliance with Authority Required procedures - Streamlined Authority Code 6182 |
| C6188 | P6188 | CN6188 | Dicloxacillin | Osteomyelitis | Compliance with Authority Required procedures - Streamlined Authority Code 6188 |
| C6189 | P6189 | CN6189 | Dutasteride with tamsulosin | Benign prostatic hyperplasia Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia. | Compliance with Authority Required procedures - Streamlined Authority Code 6189 |
| C6190 | P6190 | CN6190 | Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose Whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose | Chronic renal failure Patient must be an infant or a young child; Patient must require treatment with a low protein and a low phosphorus diet. or Patient must require treatment with a low protein, low phosphorus and low potassium diet. | Compliance with Authority Required procedures - Streamlined Authority Code 6190 |
| C6193 | P6193 | CN6193 | Protein hydrolysate formula with medium chain triglycerides | Cows' milk protein enteropathy and intolerance to soy protein Continuing treatment Must be treated by a specialist allergist, clinical immunologist, specialist | 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) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist; AND The condition must not be isolated infant colic or reflux; AND Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides; Patient must be up to the age of 24 months. | Streamlined Authority Code 6193 |
| C6194 | P6194 | CN6194 | Protein hydrolysate formula with medium chain triglycerides | Biliary atresia | Compliance with Authority Required procedures - Streamlined Authority Code 6194 |
| C6195 | P6195 | CN6195 | Protein hydrolysate formula with medium chain triglycerides | Cystic fibrosis | Compliance with Authority Required procedures - Streamlined Authority Code 6195 |
| C6196 | P6196 | CN6196 | Naproxen | Severe pain Patient must be receiving palliative care. | |
| C6197 | P6197 | CN6197 | Benzydamine | Painful mouth Patient must be receiving palliative care. | Compliance with Authority Required procedures - Streamlined Authority Code 6197 |
| C6200 | P6200 | CN6200 | Doxycycline | Severe acne | |
| C6201 | P6201 | CN6201 | Trimethoprim with sulfamethoxazole | Prophylaxis of Pneumocystis jiroveci pneumonia | Compliance with Authority Required procedures - |

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|--------------------|---------------|-----------------|---|--|---|
| | | | | | Streamlined Authority Code 6201 |
| C6202 | P6202 | CN6202 | Dutasteride | Benign prostatic hyperplasia Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia; AND The treatment must be in combination with an alpha-antagonist. | Compliance with Authority Required procedures - Streamlined Authority Code 6202 |
| C6203 | P6203 | CN6203 | Triglycerides, medium chain | Hyperlipoproteinaemia type 1 | Compliance with Authority Required procedures - Streamlined Authority Code 6203 |
| C6204 | P6204 | CN6204 | Protein hydrolysate formula with medium chain triglycerides | Cows' milk protein enteropathy and intolerance to soy protein Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist; AND The condition must not be isolated infant colic or reflux; AND Patient must have failed to respond to a strict soy-based cows' milk protein free diet; Patient must be older than 24 months of age. The name of the specialist must be documented in the patient's medical records | Compliance with Authority Required procedures - Streamlined Authority Code 6204 |
| C6205 | P6205 | CN6205 | Protein hydrolysate formula with medium chain triglycerides | Chylous ascites | Compliance with Authority Required procedures - Streamlined Authority Code 6205 |
| C6207 | P6207 | CN6207 | Hyoscine | For use in patients receiving palliative care | Compliance with Authority Required procedures - |

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|--------------------|---------------|-----------------|--|---|---|
| | | | | | Streamlined Authority Code 6207 |
| C6208 | P6208 | CN6208 | Milk powder -- synthetic | Hypercalcaemia Patient must be under the age of 4 years. | |
| C6209 | P6209 | CN6209 | Betamethasone Methylprednisolone Triamcinolone | Local intra-articular or peri-articular infiltration | |
| C6210 | P6210 | CN6210 | Betamethasone Triamcinolone | Keloid | |
| C6211 | P6211 | CN6211 | Betamethasone Triamcinolone | Chronic discoid lupus erythematosus | |
| C6212 | P6212 | CN6212 | Betamethasone | Uveitis | |
| C6213 | P6213 | CN6213 | Mefenamic acid | Menorrhagia | |
| C6214 | P6214 | CN6214 | Ibuprofen Indometacin Naproxen Piroxicam | Chronic arthropathies (including osteoarthritis) The condition must have an inflammatory component. | |
| C6217 | P6217 | CN6217 | Oxazepam | Malignant neoplasia (late stage) | Compliance with Authority Required procedures |
| C6218 | P6218 | CN6218 | Betamethasone | Corticosteroid-responsive dermatoses The condition must cover 40-60% of the patient's body surface area. | Compliance with Authority Required |

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|--------------------|---------------|-----------------|---|---|---|
| | | | Methylprednisolone Mometasone | | procedures - Streamlined Authority Code 6218 |
| C6221 | P6221 | CN6221 | Clomifene | Anovulatory infertility | |
| C6222 | P6222 | CN6222 | Interferon gamma-1b | Chronic granulomatous disease Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6222 |
| C6224 | P6224 | CN6224 | Bleomycin | Lymphoma | |
| C6225 | P6225 | CN6225 | Paracetamol | Analgesia or fever Patient must be receiving palliative care; AND Patient must be intolerant to alternative therapy. | |
| C6229 | P6229 | CN6229 | Mefenamic acid | Dysmenorrhoea | |
| C6230 | P6230 | CN6230 | Oxazepam | Anxiety Patient must be receiving this drug for the management of anxiety; AND Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility; AND Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
| C6231 | P6231 | CN6231 | Betamethasone Methylprednisolone Mometasone | Corticosteroid-responsive dermatoses The condition must cover >80% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6231 |
| C6232 | P6232 | CN6232 | Betamethasone | Corticosteroid-responsive dermatoses The condition must cover 10-20% of the patient's body surface area. | Compliance with Authority Required |

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| | | | Methylprednisolone Mometasone | | procedures - Streamlined Authority Code 6232 |
| C6234 | P6234 | CN6234 | Doxorubicin - pegylated liposomal | Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive mucocutaneous involvement. | Compliance with Authority Required procedures - Streamlined Authority Code 6234 |
| C6235 | P6235 | CN6235 | Nortriptyline | Major depression The treatment must be for use when other anti-depressant therapy has failed. | |
| C6236 | P6236 | CN6236 | Phenelzine | Depression The treatment must be for when all other anti-depressant therapy has failed. or The treatment must be for when all other anti-depressant therapy is inappropriate. | |
| C6237 | P6237 | CN6237 | Betamethasone Triamcinolone | Keloid | |
| C6240 | P6240 | CN6240 | Clomifene | Patients undergoing in-vitro fertilisation | |
| C6241 | P6241 | CN6241 | Oxybutynin Propantheline | Detrusor overactivity | |
| C6243 | P6243 | CN6243 | Oxybutynin | Detrusor overactivity Patient must be unable to tolerate oral oxybutynin. or Patient must be unable to swallow oral oxybutynin. | |
| C6244 | P6244 | CN6244 | Medroxyprogesterone | Endometriosis | |

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|--------------------|---------------|-----------------|---|---|---|
| C6246 | P6246 | CN6246 | Betamethasone Methylprednisolone Mometasone | Corticosteroid-responsive dermatoses The condition must cover 20-40% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6246 |
| C6247 | P6247 | CN6247 | Idarubicin | Acute myelogenous leukaemia (AML) | |
| C6250 | P6250 | CN6250 | Clomipramine | Cataplexy The condition must be associated with narcolepsy. | |
| C6251 | P6251 | CN6251 | Clomipramine | Obsessive-compulsive disorder | |
| C6252 | P6252 | CN6252 | Hydrocortisone | For use in a hospital | |
| C6253 | P6253 | CN6253 | Betamethasone Triamcinolone | Alopecia areata | |
| C6254 | P6254 | CN6254 | Betamethasone Triamcinolone | Granulomata The condition must be dermal. | |
| C6255 | P6255 | CN6255 | Betamethasone Triamcinolone | Lichen simplex chronicus | |
| C6256 | P6256 | CN6256 | Ibuprofen Indometacin Naproxen | Bone pain The condition must be due to malignant disease. | |
| C6257 | P6257 | CN6257 | Follitropin alfa Follitropin beta | Anovulatory infertility | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|---------------------------|----------------------|------------------------|---|---|---|
| C6262 | P6262 | CN6262 | Oxazepam | Anxiety Patient must be receiving this drug for the management of anxiety; AND Patient must be receiving long-term nursing care; AND Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult; AND Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal. | Compliance with Authority Required procedures |
| C6263 | P6263 | CN6263 | Betamethasone Methylprednisolone Mometasone | Corticosteroid-responsive dermatoses The condition must cover 60-80% of the patient's body surface area. | Compliance with Authority Required procedures - Streamlined Authority Code 6263 |
| C6265 | P6265 | CN6265 | Cladribine | Hairy cell leukaemia | Compliance with Authority Required procedures - Streamlined Authority Code 6265 |
| C6266 | P6266 | CN6266 | Fluorouracil | Patients requiring administration of fluorouracil by intravenous infusion | |
| C6268 | P6268 | CN6268 | Betamethasone Triamcinolone | Local intra-articular or peri-articular infiltration | |
| C6269 | P6269 | CN6269 | Betamethasone Triamcinolone | Necrobiosis lipidica | |
| C6273 | P6273 | CN6273 | Methylprednisolone | Local intra-articular or peri-articular infiltration | |
| C6274 | P6274 | CN6274 | Doxorubicin - pegylated liposomal | Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | AND The condition must include extensive visceral involvement. | Code 6274 |
| C6275 | P6275 | CN6275 | Bleomycin | Germ cell neoplasms | |
| C6276 | P6276 | CN6276 | Methotrexate | Patients receiving treatment with a high dose regimen | |
| C6277 | P6277 | CN6277 | Fluoxetine Fluvoxamine Paroxetine Sertraline | Obsessive-compulsive disorder | |
| C6278 | P6278 | CN6278 | Mianserin | Severe depression | |
| C6280 | P6280 | CN6280 | Paracetamol | Persistent pain The condition must be associated with osteoarthritis; Patient must identify as Aboriginal or Torres Strait Islander. | |
| C6281 | P6281 | CN6281 | Betamethasone Triamcinolone | Lichen planus hypertrophic | |
| C6282 | P6282 | CN6282 | Ibuprofen Indometacin Naproxen | Chronic arthropathies (including osteoarthritis) The condition must have an inflammatory component. | |
| C6283 | P6283 | CN6283 | Ibuprofen Indometacin Naproxen | Bone pain The condition must be due to malignant disease. | |
| C6287 | P6287 | CN6287 | Triamcinolone | Psoriasis | |

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| C6289 | P6289 | CN6289 | Sertraline | Panic disorder The treatment must be for use when other treatments have failed. or The treatment must be for use when other treatments are inappropriate. | |
| C6291 | P6291 | CN6291 | Betamethasone Triamcinolone | Lichen planus hypertrophic | |
| C6294 | P6294 | CN6294 | Darbepoetin alfa Epoetin alfa Epoetin beta Epoetin lambda Methoxy polyethylene glycol-epoetin beta | Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist. | Compliance with Authority Required procedures - Streamlined Authority Code 6294 |
| C6297 | P6297 | CN6297 | Fluorouracil | Patients requiring administration of fluorouracil by intravenous injection | |
| C6299 | P6299 | CN6299 | Clomipramine | Phobic disorders Patient must be an adult. | |
| C6300 | P6300 | CN6300 | Nortriptyline | Major depression The treatment must be for use when other anti-depressant therapy is contraindicated. | |
| C6302 | P6302 | CN6302 | Methylprednisolone | Eczema | |
| C6306 | P6306 | CN6306 | Alendronic acid with colecalciferol | Corticosteroid-induced osteoporosis Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 6306 |

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|--------------------|---------------|-----------------|---|--|---|
| | | | | The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | |
| C6307 | P6307 | CN6307 | Alendronic acid with colecalciferol | <p>Corticosteroid-induced osteoporosis</p> <p>Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6307 |
| C6308 | P6308 | CN6308 | Zoledronic acid | <p>Corticosteroid-induced osteoporosis</p> <p>Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND</p> <p>Patient must not receive more than one PBS-subsidised treatment per year.</p> <p>The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6308 |
| C6310 | P6310 | CN6310 | <p>Alendronic acid</p> <p>Risedronic acid</p> | <p>Osteoporosis</p> <p>Patient must be aged 70 years or older;</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND</p> | |

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| | | | | <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p> | |
| C6313 | P6313 | CN6313 | Zoledronic acid | <p>Osteoporosis</p> <p>Patient must be aged 70 years or older;</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND</p> <p>Patient must not receive more than one PBS-subsidised treatment per year.</p> <p>The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6313 |
| C6314 | P6314 | CN6314 | Raloxifene | <p>Established post-menopausal osteoporosis</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6314 |
| C6315 | P6315 | CN6315 | Alendronic acid with colecalciferol | <p>Established osteoporosis</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p> <p>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.</p> | Code 6315 |
| C6318 | P6318 | CN6318 | Zoledronic acid | <p>Established osteoporosis</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND</p> <p>Patient must not receive more than one PBS-subsidised treatment per year.</p> <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6318 |
| C6319 | P6319 | CN6319 | Alendronic acid with colecalciferol | <p>Established osteoporosis</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p> <p>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</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6319 |

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| | | | | to the vertebral body above or below the affected vertebral body. | |
| C6320 | P6320 | CN6320 | Alendronic acid with colecalciferol | Osteoporosis Patient must be aged 70 years or older; Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 6320 |
| C6321 | P6321 | CN6321 | Follitropin alfa Follitropin beta | Infertility The condition must be due to hypogonadotrophic hypogonadism; AND The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis; AND The treatment must be administered with human chorionic gonadotrophin. | |
| C6323 | P6323 | CN6323 | Alendronic acid Risedronic acid | Corticosteroid-induced osteoporosis Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | |
| C6324 | P6324 | CN6324 | Testosterone | Androgen deficiency Patient must not have an established pituitary or testicular disorder; AND The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs; | Compliance with Authority Required procedures |

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| | | | | <p>Patient must be aged 40 years or older;</p> <p>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.</p> <p>Androgen deficiency is defined as</p> <p>(i) testosterone level of less than 6 nmol per litre; OR</p> <p>(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 eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).</p> <p>Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.</p> <p>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.</p> <p>The name of the specialist must be included in the authority application.</p> | |
| C6325 | P6325 | CN6325 | Alendronic acid with colecalciferol | <p>Osteoporosis</p> <p>Patient must be aged 70 years or older;</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6325 |
| C6327 | P6327 | CN6327 | Alendronic acid Risedronic acid | <p>Established osteoporosis</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The fracture must have been demonstrated radiologically and the year of</p> | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | |
| C6328 | P6328 | CN6328 | Eprosartan | Drug interactions expected to occur with all of the base-priced drugs | Compliance with Authority Required procedures |
| C6329 | P6329 | CN6329 | Eprosartan | Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance | Compliance with Authority Required procedures |
| C6331 | P6331 | CN6331 | Ipratropium | Asthma Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer. | |
| C6332 | P6332 | CN6332 | Eprosartan | Drug interactions occurring with all of the base-priced drugs | Compliance with Authority Required procedures |
| C6340 | P6340 | CN6340 | Budesonide | Severe chronic asthma Patient must require long-term steroid therapy; AND Patient must not be able to use other forms of inhaled steroid therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6340 |
| C6341 | P6341 | CN6341 | Ipratropium | Chronic obstructive pulmonary disease (COPD) Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer. | |
| C6343 | P6343 | CN6343 | Loperamide | Diarrhoea | Compliance with Authority Required |

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| | | | | | procedures |
| C6345 | P6345 | CN6345 | Silver sulfadiazine | Stasis ulcers | |
| C6348 | P6348 | CN6348 | Beclometasone | Asthma Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug. | |
| C6350 | P6350 | CN6350 | Rifabutin | Mycobacterium avium complex infection Patient must be human immunodeficiency virus (HIV) positive. | Compliance with Authority Required procedures - Streamlined Authority Code 6350 |
| C6351 | P6351 | CN6351 | Eprosartan | Adverse effects occurring with all of the base-priced drugs | Compliance with Authority Required procedures |
| C6352 | P6352 | CN6352 | Tiotropium | Chronic obstructive pulmonary disease (COPD) | |
| C6355 | P6355 | CN6355 | Formoterol Salmeterol | Asthma Patient must experience frequent episodes of the condition; AND Patient must be currently receiving treatment with oral corticosteroids. or Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids. | |
| C6356 | P6356 | CN6356 | Azithromycin Rifabutin | Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre. | Compliance with Authority Required procedures - Streamlined Authority Code 6356 |
| C6359 | P6359 | CN6359 | Dantrolene | Chronic spasticity | |
| C6362 | P6362 | CN6362 | Silver sulfadiazine | Infection | |

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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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| | | | | Prevention and treatment The condition must be in partial or full skin thickness loss due to burns. or The condition must be in partial or full skin thickness loss due to epidermolysis bullosa. | |
| C6364 | P6364 | CN6364 | Loperamide | Diarrhoea Patient must identify as Aboriginal or Torres Strait Islander. | Compliance with Authority Required procedures - Streamlined Authority Code 6364 |
| C6366 | P6366 | CN6366 | Indacaterol | Chronic obstructive pulmonary disease (COPD) | |
| C6367 | P6367 | CN6367 | Salbutamol | Bronchospasm Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug. | |
| C6368 | P6368 | CN6368 | Naproxen | Chronic arthropathies (including osteoarthritis) The condition must have an inflammatory component. | |
| C6369 | P6369 | CN6369 | Octreotide | Vasoactive intestinal peptide secreting tumour (VIPoma) The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 6369 |
| C6370 | P6370 | CN6370 | Aprepitant | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used | Compliance with Authority Required |

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| | | | | <p>to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> <p>Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.</p> | procedures - Streamlined Authority Code 6370 |
| C6377 | P6377 | CN6377 | Darunavir with cobicistat | <p>Human immunodeficiency virus (HIV) infection</p> <p>The treatment must be in addition to optimised background therapy; AND</p> <p>The treatment must be in combination with other antiretroviral agents; AND</p> <p>The treatment must not be in combination with ritonavir; AND</p> <p>Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6377 |
| C6383 | P6383 | CN6383 | Aprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> <p>Concomitant use of a 5HT3 antagonist should not occur with aprepitant on</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6383 |

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| | | | | days 2 and 3 of any chemotherapy cycle. | |
| C6387 | P6387 | CN6387 | Naproxen | Bone pain The condition must be due to malignant disease. | |
| C6390 | P6390 | CN6390 | Octreotide | Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 6390 |
| C6394 | P6394 | CN6394 | Desferrioxamine | Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload. | Compliance with Authority Required procedures - Streamlined Authority Code 6394 |
| C6395 | P6395 | CN6395 | Terbinafine | Onychomycosis The condition must be proximal or extensive (greater than 80% nail involvement); AND Patient must have failed to respond to topical treatment; AND The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider. or The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider. The date of the pathology report must be provided at the time of application and must not be more than 12 months old | Compliance with Authority Required procedures |

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| C6403 | P6403 | CN6403 | Deferiprone | Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective. | Compliance with Authority Required procedures - Streamlined Authority Code 6403 |
| C6404 | P6404 | CN6404 | Terbinafine | Dermatophyte infection Patient must have failed to respond to topical treatment; Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures |
| C6409 | P6409 | CN6409 | Leuprorelin Triptorelin | Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate | |
| C6412 | P6412 | CN6412 | Terbinafine | Fungal or yeast infection The condition must be fungal; or The condition must be due to yeast; Patient must be 18 years of age or less. | Compliance with Authority Required procedures - Streamlined Authority Code 6412 |
| C6413 | P6413 | CN6413 | Darunavir with cobicistat | Human immunodeficiency virus (HIV) infection Initial treatment Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must not be in combination with ritonavir. | Compliance with Authority Required procedures - Streamlined Authority Code 6413 |
| C6428 | P6428 | CN6428 | Darunavir with cobicistat | Human immunodeficiency virus (HIV) infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents; AND The treatment must not be in combination with ritonavir. | Compliance with Authority Required procedures - Streamlined Authority Code 6428 |
| C6434 | P6434 | CN6434 | Miconazole | Fungal or yeast infection | Compliance with Authority Required |

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| | | | Terbinafine | Patient must be an Aboriginal or a Torres Strait Islander person. | procedures - Streamlined Authority Code 6434 |
| C6444 | P6444 | CN6444 | Aprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND</p> <p>Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.</p> <p>No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.</p> <p>Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6444 |
| C6448 | P6448 | CN6448 | Deferiprone | <p>Iron overload</p> <p>Patient must have thalassaemia major; AND</p> <p>Patient must be unable to take desferrioxamine therapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6448 |
| C6453 | P6453 | CN6453 | Terbinafine | <p>Dermatophyte infection</p> <p>Patient must have failed to respond to topical treatment; AND</p> <p>Patient must have failed to respond to griseofulvin;</p> <p>Patient must be 18 years of age or less.</p> | Compliance with Authority Required procedures |

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| C6463 | P6463 | CN6463 | Naproxen | Chronic arthropathies (including osteoarthritis) The condition must have an inflammatory component. | |
| C6464 | P6464 | CN6464 | Aprepitant | Nausea and vomiting The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed. No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle. | Compliance with Authority Required procedures - Streamlined Authority Code 6464 |
| C6471 | P6471 | CN6471 | Naproxen | Bone pain The condition must be due to malignant disease. | |
| C6475 | P6475 | CN6475 | Liothyronine | Hypothyroidism The condition must be severe hypothyroidism; AND The treatment must be for initiation of therapy only. | Compliance with Authority Required procedures - Streamlined Authority Code 6475 |
| C6517 | P6517 | CN6517 | Nafarelin | Endometriosis Subsequent treatment, for up to 6 months | |

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| | | | | <p>The condition must be visually proven; AND</p> <p>The treatment must not be within 2 years of the end of the previous course of treatment with this drug; AND</p> <p>Patient must have had a recent bone density assessment.</p> <p>The date of the bone density assessment must be recorded in the patient's medical records.</p> | |
| C6524 | P6524 | CN6524 | Denosumab | <p>Established osteoporosis</p> <p>Patient must have fracture due to minimal trauma; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6524 |
| C6548 | P6548 | CN6548 | Denosumab | <p>Osteoporosis</p> <p>Patient must be aged 70 years or older;</p> <p>Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND</p> <p>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</p> <p>The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6548 |
| C6552 | P6552 | CN6552 | Nafarelin | <p>Endometriosis</p> <p>Initial treatment, for up to 6 months</p> <p>The condition must be visually proven.</p> | |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| C6562 | P6562 | CN6562 | Ipilimumab | <p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Induction treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have received prior treatment with ipilimumab; AND</p> <p>The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6562 |
| C6578 | P6578 | CN6578 | Lenvatinib | <p>Locally advanced or metastatic differentiated thyroid cancer</p> <p>Continuing treatment</p> <p>The condition must be refractory to radioactive iodine; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6578 |
| C6585 | P6585 | CN6585 | Ipilimumab | <p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Re-induction treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction); AND</p> <p>The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.</p> <p>An initial objective response to treatment is defined as either</p> <p>(i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6585 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | recent course of ipilimumab; or (ii) a partial or complete response. The patient's body weight must be documented in the patient's medical records at the time treatment with ipilimumab is initiated. | |
| C6621 | P6621 | CN6621 | Filgrastim | Severe chronic neutropenia Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; or Patient must have neutrophil dysfunction; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months. or Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 6621 |
| C6628 | P6628 | CN6628 | Ciclosporin | Management of transplant rejection The treatment must be used by organ or tissue transplant recipients. | Compliance with Authority Required procedures - Streamlined Authority Code 6628 |
| C6631 | P6631 | CN6631 | Ciclosporin | Nephrotic syndrome Management (initiation, stabilisation and review of therapy) Patient must have failed prior treatment with steroids and cytostatic drugs; or Patient must be intolerant to treatment with steroids and cytostatic drugs; or The condition must be considered inappropriate for treatment with steroids and cytostatic drugs; AND Patient must not have renal impairment; AND Must be treated by a nephrologist. | Compliance with Authority Required procedures - Streamlined Authority Code 6631 |
| C6636 | P6636 | CN6636 | Paroxetine | Panic disorder | |
| C6638 | P6638 | CN6638 | Ciclosporin | Severe active rheumatoid arthritis | Compliance with |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | Management (initiation, stabilisation and review of therapy) The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); or The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate); AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist. | Authority Required procedures - Streamlined Authority Code 6638 |
| C6640 | P6640 | CN6640 | Filgrastim | Chronic cyclical neutropenia Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics. or Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 6640 |
| C6643 | P6643 | CN6643 | Ciclosporin | Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 6643 |
| C6647 | P6647 | CN6647 | Mupirocin | Staphylococcus aureus infection Patient must have nasal colonisation with the bacteria; Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 6647 |
| C6653 | P6653 | CN6653 | Filgrastim | Mobilisation of peripheral blood progenitor cells The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6653 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|---------------------------|----------------------|------------------------|---|---|---|
| C6654 | P6654 | CN6654 | Filgrastim | Mobilisation of peripheral blood progenitor cells The treatment must be in a normal volunteer for use in allogeneic transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 6654 |
| C6655 | P6655 | CN6655 | Filgrastim | Assisting autologous peripheral blood progenitor cell transplantation The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 6655 |
| C6658 | P6658 | CN6658 | Milk protein and fat formula with vitamins and minerals -- carbohydrate free Soy protein and fat formula with vitamins and minerals -- carbohydrate free | Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet. or Patient must have a glucose transport protein defect. or Patient must have pyruvate dehydrogenase deficiency. or Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance. | |
| C6660 | P6660 | CN6660 | Ciclosporin | Severe atopic dermatitis Management (initiation, stabilisation and review of therapy) Must be treated by a dermatologist; or Must be treated by a clinical immunologist; AND The condition must be ineffective to other systemic therapies. or The condition must be inappropriate for other systemic therapies. | Compliance with Authority Required procedures - Streamlined Authority Code 6660 |
| C6666 | P6666 | CN6666 | Montelukast | Asthma First-line prevention Patient must be aged 2 to 5 years inclusive; The condition must be frequent intermittent; or The condition must be mild persistent; AND The treatment must be the single preventer agent; AND | Compliance with Authority Required procedures - Streamlined Authority Code 6666 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | The treatment must be an alternative to sodium cromoglycate. or The treatment must be an alternative to nedocromil sodium. | |
| C6674 | P6674 | CN6674 | Montelukast | Asthma First-line prevention The condition must be frequent intermittent; or The condition must be mild persistent; AND The treatment must be the single preventer agent; AND The treatment must be an alternative to sodium cromoglycate; or The treatment must be an alternative to nedocromil sodium; Patient must be aged 6 to 14 years inclusive. | Compliance with Authority Required procedures - Streamlined Authority Code 6674 |
| C6679 | P6679 | CN6679 | Filgrastim | Assisting bone marrow transplantation Patient must be receiving marrow-ablative chemotherapy prior to the transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 6679 |
| C6680 | P6680 | CN6680 | Filgrastim | Severe congenital neutropenia Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; AND Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage. | Compliance with Authority Required procedures - Streamlined Authority Code 6680 |
| C6683 | P6683 | CN6683 | Citrulline with carbohydrate | Urea cycle disorders The treatment must be for preventing low plasma arginine levels. or The treatment must be for preventing low citrulline levels. | |
| C6696 | P6696 | CN6696 | Ixekizumab Risankizumab Secukinumab | Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks | 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) |
|--------------------|---------------|-----------------|---------------|---|---|
| | | | | <p>treatment; or</p> <p>Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Must be treated by a dermatologist.</p> | |
| C6706 | P6706 | CN6706 | Bromocriptine | <p>Pathological hyperprolactinaemia</p> <p>Patient must have had surgery for this condition with incomplete resolution.</p> | |
| C6707 | P6707 | CN6707 | Bromocriptine | <p>Pathological hyperprolactinaemia</p> <p>Patient must be one in whom radiotherapy is not indicated.</p> | |
| C6717 | P6717 | CN6717 | Bromocriptine | Acromegaly | |
| C6718 | P6718 | CN6718 | Bromocriptine | Parkinson disease | |
| C6719 | P6719 | CN6719 | Bromocriptine | <p>Pathological hyperprolactinaemia</p> <p>Patient must have had radiotherapy for this condition with incomplete resolution.</p> | |
| C6752 | P6752 | CN6752 | Trametinib | <p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Continuing treatment</p> <p>Patient must have previously been issued with an authority prescription for this drug; AND</p> <p>Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition; AND</p> <p>Patient must have stable or responding disease.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6752 |
| C6773 | P6773 | CN6773 | Alprazolam | <p>Panic disorder</p> <p>The treatment must be for use when other treatments have failed. or</p> <p>The treatment must be for use when other treatments are inappropriate.</p> | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| C6786 | P6786 | CN6786 | Electrolyte replacement, oral | Rehydration in intestinal failure | Compliance with Authority Required procedures |
| C6787 | P6787 | CN6787 | Bromocriptine | Pathological hyperprolactinaemia Patient must be one in whom surgery is not indicated. | |
| C6803 | P6803 | CN6803 | Cobimetinib | Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition; AND Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 6803 |
| C6809 | P6809 | CN6809 | Calcipotriol with betamethasone | Chronic stable plaque type psoriasis vulgaris The condition must be inadequately controlled by potent topical corticosteroid monotherapy. | |
| C6812 | P6812 | CN6812 | Ferrous fumarate Ferrous fumarate with folic acid | For treatment of a patient identifying as Aboriginal or Torres Strait Islander | |
| C6815 | P6815 | CN6815 | Salbutamol | Asthma Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer. | |
| C6825 | P6825 | CN6825 | Salbutamol | Chronic obstructive pulmonary disease (COPD) Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer. | |
| C6847 | P6847 | CN6847 | Alemtuzumab | Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---------------|--|---|
| | | | | <p>Patient must not show continuing progression of disability while on treatment with this drug; AND</p> <p>Patient must not receive more than one PBS-subsidised treatment per year; AND</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must have demonstrated compliance with, and an ability to tolerate this therapy; AND</p> <p>Must be treated by a neurologist.</p> | Code 6847 |
| C6852 | P6852 | CN6852 | Fosaprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.</p> <p>No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.</p> <p>Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6852 |
| C6871 | P6871 | CN6871 | Varenicline | <p>Nicotine dependence</p> <p>Commencement of a short-term (12 weeks or 24 weeks) course of treatment</p> <p>The treatment must be as an aid to achieving abstinence from smoking; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have indicated they are ready to cease smoking; AND</p> <p>Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period; AND</p> <p>Patient must be undergoing concurrent counselling for smoking cessation</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6871 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested. | |
| C6881 | P6881 | CN6881 | Bupropion | Nicotine dependence Completion of a short-term (9 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment; AND Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period; AND Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program. | Compliance with Authority Required procedures - Streamlined Authority Code 6881 |
| C6882 | P6882 | CN6882 | Bupropion | Nicotine dependence Commencement of a short-term (9 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have indicated they are ready to cease smoking; AND Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period; AND Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time PBS-subsidised treatment is initiated. Details of the support and counselling program must be documented in the | Compliance with Authority Required procedures - Streamlined Authority Code 6882 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---------------|---|---|
| | | | | patient's medical records at the time treatment is initiated. | |
| C6885 | P6885 | CN6885 | Varenicline | <p>Nicotine dependence</p> <p>Completion of a short-term (24 weeks) course of treatment</p> <p>The treatment must be as an aid to achieving abstinence from smoking; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug during this current course of treatment; AND</p> <p>Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment; AND</p> <p>Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6885 |
| C6886 | P6886 | CN6886 | Fosaprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND</p> <p>Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.</p> <p>No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6886 |
| C6887 | P6887 | CN6887 | Fosaprepitant | <p>Nausea and vomiting</p> <p>The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy; AND</p> <p>The treatment must be in combination with a 5-hydroxytryptamine receptor</p> | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle; AND Patient must have had a prior episode of chemotherapy induced nausea or vomiting; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed. No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle. | Code 6887 |
| C6890 | P6890 | CN6890 | Protein formula with carbohydrate, fat, vitamins and minerals | Dietary management of conditions requiring a source of medium chain triglycerides Patient must have fat malabsorption due to liver disease; or Patient must have fat malabsorption due to short gut syndrome; or Patient must have fat malabsorption due to cystic fibrosis; or Patient must have fat malabsorption due to gastrointestinal disorders; Patient must be aged from 1 to 10 years inclusive. | |
| C6891 | P6891 | CN6891 | Fosaprepitant | Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer; AND The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline. No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6891 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------|--|---|
| C6898 | P6898 | CN6898 | Risperidone | Severe behavioural disturbances Patient must have autism spectrum disorder; AND The treatment must be under the supervision of a paediatrician or psychiatrist; AND The treatment must be in combination with non-pharmacological measures; Patient must be under 18 years of age. Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful. The diagnosis of autism spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders. | Compliance with Authority Required procedures - Streamlined Authority Code 6898 |
| C6910 | P6910 | CN6910 | Testosterone | Androgen deficiency Patient must have an established pituitary or testicular disorder; AND Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C6911 | P6911 | CN6911 | Baclofen | Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; or Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease. | Compliance with Authority Required procedures - Streamlined Authority Code 6911 |
| C6919 | P6919 | CN6919 | Testosterone | Pubertal induction Patient must be under 18 years of age; Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------|--|---|
| | | | | the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | |
| C6925 | P6925 | CN6925 | Baclofen | Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; or Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin. | Compliance with Authority Required procedures - Streamlined Authority Code 6925 |
| C6933 | P6933 | CN6933 | Testosterone | Micropenis Patient must be under 18 years of age; Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C6934 | P6934 | CN6934 | Testosterone | Constitutional delay of growth or puberty Patient must be under 18 years of age; Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C6939 | P6939 | CN6939 | Baclofen | Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; or Patient must have had unacceptable side effects to treatment with oral | Compliance with Authority Required procedures - Streamlined Authority |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis. | Code 6939 |
| C6940 | P6940 | CN6940 | Baclofen | Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; or Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury. | Compliance with Authority Required procedures - Streamlined Authority Code 6940 |
| C6952 | P6952 | CN6952 | Degarelix | Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate | |
| C6953 | P6953 | CN6953 | Botulinum toxin type A purified neurotoxin complex | Urinary incontinence Must be treated by a urologist; or Must be treated by a gynaecologist; AND The condition must be due to idiopathic overactive bladder; AND The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents; AND Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex; AND Patient must be willing and able to self-catheterise; AND The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment; Patient must be aged 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 6953 |
| C6976 | P6976 | CN6976 | Degarelix | Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate | |
| C6979 | P6979 | CN6979 | Chorionic gonadotrophin | Combined deficiency of human growth hormone and gonadotrophins Patient must be male; Patient must be one in whom the absence of secondary sexual | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | characteristics indicates a lag in maturation. | |
| C6980 | P6980 | CN6980 | Tenofovir | Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must be nucleoside analogue naive; AND Patient must have detectable HBV DNA; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6980 |
| C6982 | P6982 | CN6982 | Tenofovir | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6982 |
| C6983 | P6983 | CN6983 | Tenofovir | Chronic hepatitis B infection Patient must have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have detectable HBV DNA. Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6983 |
| C6984 | P6984 | CN6984 | Tenofovir | Chronic hepatitis B infection Patient must not have cirrhosis; AND Patient must have failed antihepadnaviral therapy; AND Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection. or Patient must have repeatedly elevated HBV DNA levels one log greater than | Compliance with Authority Required procedures - Streamlined Authority Code 6984 |

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| | | | | the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance. | |
| C6985 | P6985 | CN6985 | Tenofovir with emtricitabine | HIV infection Initial Patient must be antiretroviral treatment naive; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6985 |
| C6986 | P6986 | CN6986 | Tenofovir with emtricitabine | HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 6986 |
| C6987 | P6987 | CN6987 | Chorionic gonadotrophin | Infertility Patient must be male; The condition must be due to hypogonadotrophic hypogonadism. | |
| C6989 | P6989 | CN6989 | Chorionic gonadotrophin | Anovulatory infertility | |
| C6990 | P6990 | CN6990 | Chorionic gonadotrophin | Infertility Patient must be male; The condition must be associated with isolated luteinising hormone deficiency. | |
| C6991 | P6991 | CN6991 | Chorionic gonadotrophin | Assisted Reproductive Technology Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 6991 |
| C6992 | P6992 | CN6992 | Tenofovir | Chronic hepatitis B infection Patient must not have cirrhosis; AND | Compliance with Authority Required procedures - |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------------------|---|---|
| | | | | <p>Patient must be nucleoside analogue naive; AND</p> <p>Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; or</p> <p>Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; AND</p> <p>Patient must have evidence of chronic liver injury determined by:</p> <p>(i) confirmed elevated serum ALT; or (ii) liver biopsy; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> | Streamlined Authority Code 6992 |
| C6995 | P6995 | CN6995 | Chorionic gonadotrophin | <p>Hypogonadism or delayed puberty</p> <p>Patient must be male;</p> <p>Patient must be aged 16 years or older;</p> <p>Patient must show clinical evidence of the condition; AND</p> <p>The treatment must not extend beyond 6 months.</p> | |
| C6998 | P6998 | CN6998 | Tenofovir | <p>HIV infection</p> <p>Initial</p> <p>Patient must be antiretroviral treatment naive; AND</p> <p>The treatment must be in combination with other antiretroviral agents.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 6998 |
| C7025 | P7025 | CN7025 | Lanreotide | <p>Acromegaly</p> <p>The condition must be active; AND</p> <p>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND</p> <p>The treatment must be after failure of other therapy including dopamine agonists; or</p> <p>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</p> <p>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7025 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.</p> <p>In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.</p> | |
| C7134 | P7134 | CN7134 | Baclofen | <p>Severe chronic spasticity</p> <p>Patient must have failed to respond to treatment with oral antispastic agents; or</p> <p>Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND</p> <p>Patient must have chronic spasticity due to multiple sclerosis.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7134 |
| C7148 | P7148 | CN7148 | Baclofen | <p>Severe chronic spasticity</p> <p>Patient must have failed to respond to treatment with oral antispastic agents; or</p> <p>Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND</p> <p>Patient must have chronic spasticity due to spinal cord disease.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7148 |
| C7152 | P7152 | CN7152 | Baclofen | <p>Severe chronic spasticity</p> <p>Patient must have failed to respond to treatment with oral antispastic agents; or</p> <p>Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND</p> <p>Patient must have chronic spasticity of cerebral origin.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7152 |
| C7153 | P7153 | CN7153 | Baclofen | <p>Severe chronic spasticity</p> <p>Patient must have failed to respond to treatment with oral antispastic agents; or</p> | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury. | Code 7153 |
| C7164 | P7164 | CN7164 | Goserelin | Anticipated premature ovarian failure Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure; AND Patient must not receive more than 6 months' of treatment for this condition in a lifetime; Patient must be pre-menopausal. | |
| C7258 | P7258 | CN7258 | Eribulin | Advanced (unresectable and/or metastatic) liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND The condition must be dedifferentiated, myxoid, round-cell or pleomorphic subtype; AND Patient must have received prior chemotherapy treatment including an anthracycline and ifosfamide (unless contraindicated) for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; Patient must be aged 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 7258 |
| C7273 | P7273 | CN7273 | Icatibant | Anticipated emergency treatment of an acute attack of hereditary angioedema Initial Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency; AND Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema; AND The condition must be assessed by a clinical immunologist. or The condition must be assessed by a respiratory physician. or The condition must be assessed by a specialist allergist. or The condition must be assessed by a general physician experienced in the | 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) |
|--------------------|---------------|-----------------|---|---|---|
| | | | | management of patients with hereditary angioedema. The name of the specialist consulted must be provided at the time of application for initial supply. The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application. | |
| C7274 | P7274 | CN7274 | Icatibant | Anticipated emergency treatment of an acute attack of hereditary angioedema Continuing Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C7275 | P7275 | CN7275 | Vitamins, minerals and trace elements formula | Dietary management of conditions requiring a highly restrictive therapeutic diet Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet; AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations; Patient must be aged 3 years or older. | |
| C7280 | P7280 | CN7280 | Eribulin | Advanced (unresectable and/or metastatic) liposarcoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop progressive disease while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; Patient must be aged 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 7280 |
| C7346 | P7346 | CN7346 | Alectinib Brigatinib Ceritinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | |
| C7362 | P7362 | CN7362 | Mannitol | <p>Cystic fibrosis</p> <p>The treatment must be as monotherapy; AND</p> <p>Patient must be intolerant or inadequately responsive to dornase alfa;</p> <p>Patient must be 6 years of age or older.</p> <p>Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.</p> <p>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.</p> <p>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment</p> <p>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND</p> <p>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7362 |
| C7367 | P7367 | CN7367 | Mannitol | Cystic fibrosis | Compliance with Authority Required |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>The treatment must be in combination with dornase alfa; AND</p> <p>Patient must be inadequately responsive to dornase alfa; AND</p> <p>Patient must have trialled hypertonic saline for this condition;</p> <p>Patient must be 6 years of age or older.</p> <p>Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.</p> <p>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.</p> <p>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment</p> <p>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND</p> <p>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.</p> | procedures - Streamlined Authority Code 7367 |
| C7374 | P7374 | CN7374 | Deferasirox | <p>Chronic iron overload</p> <p>Initial treatment</p> <p>Patient must not be transfusion dependent; AND</p> <p>The condition must be thalassaemia.</p> | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| C7375 | P7375 | CN7375 | Deferasirox | Chronic iron overload Initial treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis. | Compliance with Authority Required procedures |
| C7385 | P7385 | CN7385 | Deferasirox | Chronic iron overload Initial treatment Patient must be red blood cell transfusion dependent; AND Patient must have a serum ferritin level of greater than 1000 microgram/L; AND Patient must have a malignant disorder of haemopoiesis; AND Patient must have a median life expectancy exceeding five years. | Compliance with Authority Required procedures |
| C7386 | P7386 | CN7386 | Ocrelizumab | Multiple sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not show continuing progression of disability while on treatment with this drug; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy; AND Must be treated by a neurologist. | Compliance with Authority Required procedures - Streamlined Authority Code 7386 |
| C7431 | P7431 | CN7431 | Everolimus | Tuberous sclerosis complex (TSC) Continuing treatment The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; or The condition must be visceral tumours associated with TSC; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 7431 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>Patient must have received an initial authority prescription for this drug for this condition; AND</p> <p>Patient must have demonstrated a response to prior treatment.</p> | |
| C7432 | P7432 | CN7432 | Everolimus | <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Continuing treatment beyond 3 months</p> <p>Patient must have received an initial authority prescription for this drug for this condition; AND</p> <p>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7432 |
| C7433 | P7433 | CN7433 | Axitinib | <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Continuing treatment beyond 3 months</p> <p>Patient must have received an initial authority prescription for this drug for this condition; AND</p> <p>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7433 |
| C7446 | P7446 | CN7446 | Erlotinib | <p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)</p> <p>Continuing treatment</p> <p>The treatment must be as monotherapy; AND</p> <p>Patient must have received an initial authority prescription for this drug for this condition; AND</p> <p>Patient must not have progressive disease;</p> <p>Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7446 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

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|--------------------|---------------|-----------------|-------------|--|---|
| | | | | tyrosine kinase inhibitors in tumour material. | |
| C7447 | P7447 | CN7447 | Gefitinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have received an initial authority prescription for this drug for this condition; AND Patient must not have progressive disease. | Compliance with Authority Required procedures - Streamlined Authority Code 7447 |
| C7458 | P7458 | CN7458 | Pazopanib | Advanced (unresectable and/or metastatic) soft tissue sarcoma Continuing treatment beyond 3 months Patient must have received an initial authority prescription for this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7458 |
| C7459 | P7459 | CN7459 | Pazopanib | Advanced (unresectable and/or metastatic) soft tissue sarcoma Continuing treatment beyond 3 months Patient must have received an initial authority prescription for this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND Patient must require dose adjustment; AND The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7459 |
| C7471 | P7471 | CN7471 | Sunitinib | Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Continuing treatment Patient must have received an initial authority prescription for this drug for this condition; AND Patient must not have disease progression; AND | Compliance with Authority Required procedures - Streamlined Authority Code 7471 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|----------------|--|---|
| | | | | The treatment must be as monotherapy. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | |
| C7483 | P7483 | CN7483 | Varenicline | Nicotine dependence Continuation of a short-term (12 weeks or 24 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received treatment with this drug during this current course of treatment; AND Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program. | Compliance with Authority Required procedures - Streamlined Authority Code 7483 |
| C7484 | P7484 | CN7484 | Tetracosactide | Hypsarhythmia and/or infantile spasms | |
| C7487 | P7487 | CN7487 | Sorafenib | Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment beyond 3 months Patient must have received an initial authority prescription for this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 7487 |
| C7488 | P7488 | CN7488 | Methotrexate | Severe active rheumatoid arthritis Patient must be unsuitable for administration of an oral form of methotrexate for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7488 |
| C7491 | P7491 | CN7491 | Sonidegib | Metastatic or locally advanced basal cell carcinoma (BCC) | Compliance with |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---------------|--|---|
| | | | Vismodegib | Initial treatment or Continuing treatment – balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; or Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Authority Required procedures |
| C7518 | P7518 | CN7518 | Methotrexate | Severe psoriasis The condition must not have adequately responded to topical treatment; AND Patient must be unsuitable for administration of an oral form of methotrexate for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7518 |
| C7526 | P7526 | CN7526 | Pralatrexate | Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma Continuing treatment The condition must be relapsed or chemotherapy refractory; AND Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C7558 | P7558 | CN7558 | Pralatrexate | Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma Initial treatment The condition must be relapsed or chemotherapy refractory; AND Patient must have undergone appropriate prior front-line curative intent chemotherapy. | Compliance with Authority Required procedures |
| C7566 | P7566 | CN7566 | Dexamethasone | Non-infectious posterior segment uveitis Must be treated by an ophthalmologist or in consultation with an ophthalmologist; AND Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 6/12 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) |
|--------------------|---------------|-----------------|-------------------------------|---|---|
| | | | | worse in the eye proposed for treatment, secondary to vitreous haze or macular oedema; AND Patient must have unilateral, asymmetric or bilateral flare-up where systemic treatment or further intensification of systemic treatment is not clinically indicated. | |
| C7593 | P7593 | CN7593 | Glecaprevir with pibrentasvir | Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND The treatment must be limited to a maximum duration of 8 weeks. | Compliance with Authority Required procedures |
| C7613 | P7613 | CN7613 | Afatinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material. | Compliance with Authority Required procedures - Streamlined Authority Code 7613 |
| C7615 | P7615 | CN7615 | Glecaprevir with pibrentasvir | Chronic hepatitis C infection Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND | Compliance with Authority Required procedures |

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Clause 1

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|--------------------|---------------|-----------------|-------------|---|---|
| | | | | The treatment must be limited to a maximum duration of 12 weeks. | |
| C7699 | P7699 | CN7699 | Ocrelizumab | <p>Multiple sclerosis Initial treatment</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or</p> <p>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</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>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</p> <p>Patient must be ambulatory (without assistance or support); AND</p> <p>Must be treated by a neurologist.</p> <p>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7699 |
| C7714 | P7714 | CN7714 | Alemtuzumab | <p>Multiple sclerosis Initial treatment</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or</p> <p>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</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7714 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| | | | | <p>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</p> <p>Patient must be ambulatory (without assistance or support); AND</p> <p>Must be treated by a neurologist.</p> <p>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.</p> | |
| C7781 | P7781 | CN7781 | Montelukast | <p>Asthma</p> <p>Prevention of condition</p> <p>The condition must be exercise-induced; AND</p> <p>The treatment must be as an alternative to adding salmeterol xinafoate; or</p> <p>The treatment must be an alternative to adding formoterol fumarate; AND</p> <p>The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid; AND</p> <p>Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms;</p> <p>Patient must be aged 6 to 14 years inclusive.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7781 |
| C7789 | P7789 | CN7789 | Perampanel | <p>Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition;</p> <p>Patient must be aged 12 years or older.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7789 |
| C7798 | P7798 | CN7798 | <p>Acclidinium with formoterol</p> <p>Indacaterol with glycopyrronium</p> <p>Tiotropium with olodaterol</p> <p>Umeclidinium with vilanterol</p> | <p>Chronic obstructive pulmonary disease (COPD)</p> <p>Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA). or</p> <p>Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA). or</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7798 |

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Clause 1

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|--------------------|---------------|-----------------|--|--|---|
| | | | | Patient must have been stabilised on a combination of a LAMA and a LABA. | |
| C7822 | P7822 | CN7822 | Filgrastim Lipegfilgrastim Pegfilgrastim | Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia. or Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 7822 |
| C7843 | P7843 | CN7843 | Filgrastim Lipegfilgrastim Pegfilgrastim | Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia. or Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 7843 |
| C7876 | P7876 | CN7876 | Atomoxetine | Attention deficit hyperactivity disorder Initial treatment Must be treated by a paediatrician or psychiatrist; AND The condition must be or have been diagnosed according to the DSM-5 criteria; AND Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; or Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; or Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; or Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously); | Compliance with Authority Required procedures - Streamlined Authority Code 7876 |

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------|--|---|
| | | | | Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive. | |
| C7890 | P7890 | CN7890 | Atomoxetine | Attention deficit hyperactivity disorder Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7890 |
| C7927 | P7927 | CN7927 | Quetiapine | Acute mania The condition must be associated with bipolar I disorder; AND The treatment must be as monotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 7927 |
| C7943 | P7943 | CN7943 | Bendamustine | Previously untreated stage II bulky or stage III or IV indolent non-Hodgkin's lymphoma Induction treatment The condition must be CD20 positive; AND The condition must be previously untreated; AND The condition must be symptomatic; AND The treatment must be for induction treatment purposes only; AND The treatment must be in combination with rituximab or obinutuzumab; AND The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 7943 |
| C7944 | P7944 | CN7944 | Bendamustine | Follicular lymphoma Re-induction treatment The condition must be CD20 positive; AND The condition must be refractory to treatment with rituximab for this condition; AND The condition must be symptomatic; AND The treatment must be for re-induction treatment purposes only; AND | Compliance with Authority Required procedures - Streamlined Authority Code 7944 |

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| | | | | <p>The treatment must be in combination with obinutuzumab; AND</p> <p>The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.</p> <p>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.</p> | |
| C7970 | P7970 | CN7970 | Budesonide with formoterol | <p>Asthma</p> <p>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids. or</p> <p>Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy. or</p> <p>Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7970 |
| C7972 | P7972 | CN7972 | Bendamustine | <p>Previously untreated stage III or IV mantle cell lymphoma</p> <p>Induction treatment</p> <p>The condition must be CD20 positive; AND</p> <p>The treatment must be in combination with rituximab; AND</p> <p>The condition must be previously untreated; AND</p> <p>The condition must be symptomatic; AND</p> <p>The treatment must be for induction treatment purposes only; AND</p> <p>Patient must not receive more than 6 cycles (12 doses) of treatment under this restriction; AND</p> <p>Patient must not be eligible for stem cell transplantation.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 7972 |
| C7979 | P7979 | CN7979 | Budesonide with formoterol | <p>Asthma</p> <p>Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.</p> | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | | Code 7979 |
| C8161 | P8161 | CN8161 | Octreotide | <p>Acromegaly</p> <p>The condition must be controlled with octreotide immediate release injections; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.</p> <p>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8161 |
| C8165 | P8165 | CN8165 | Octreotide | <p>Acromegaly</p> <p>The condition must be active; AND</p> <p>Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND</p> <p>The treatment must be after failure of other therapy including dopamine agonists; or</p> <p>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</p> <p>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.</p> <p>In a patient treated with radiotherapy, octreotide should be withdrawn every</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8165 |

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| | | | | 2 years in the 10 years after radiotherapy for assessment of remission | |
| C8183 | P8183 | CN8183 | Trifluridine with tipiracil | <p>Metastatic colorectal cancer</p> <p>Continuing treatment</p> <p>Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8183 |
| C8197 | P8197 | CN8197 | Octreotide | <p>Acromegaly</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must be controlled with octreotide immediate release injections; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.</p> <p>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8197 |
| C8198 | P8198 | CN8198 | Octreotide | <p>Vasoactive intestinal peptide secreting tumour (VIPoma)</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved symptom control on octreotide immediate release injections; AND</p> <p>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8198 |

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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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| | | | | Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | |
| C8208 | P8208 | CN8208 | Octreotide | <p>Functional carcinoid tumour</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved symptom control on octreotide immediate release injections; AND</p> <p>The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.</p> <p>Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8208 |
| C8214 | P8214 | CN8214 | Dolutegravir with rilpivirine | <p>HIV infection</p> <p>Initial treatment</p> <p>Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8214 |
| C8226 | P8226 | CN8226 | Dolutegravir with rilpivirine | <p>HIV infection</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8226 |
| C8288 | P8288 | CN8288 | Tolvaptan | <p>Autosomal dominant polycystic kidney disease (ADPKD)</p> <p>Continuing treatment</p> <p>Must be treated by a nephrologist or in consultation with a nephrologist; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8288 |

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| | | | | Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73m ² ; AND Patient must not have had a kidney transplant. | |
| C8326 | P8326 | CN8326 | Deferasirox | Chronic iron overload Continuing treatment Patient must be red blood cell transfusion dependent; AND Patient must have a malignant disorder of haemopoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8326 |
| C8328 | P8328 | CN8328 | Deferasirox | Chronic iron overload Continuing treatment Patient must be transfusion dependent; AND Patient must not have a malignant disorder of erythropoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8328 |
| C8329 | P8329 | CN8329 | Deferasirox | Chronic iron overload Continuing treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8329 |
| C8544 | P8544 | CN8544 | Guanfacine | Attention deficit hyperactivity disorder Initial treatment Must be treated by a paediatrician or psychiatrist; AND The condition must be or have been diagnosed according to the DSM-5 criteria; AND Patient must be receiving a maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) which has been stable for at least four weeks; AND | Compliance with Authority Required procedures - Streamlined Authority Code 8544 |

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| | | | | <p>The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine); AND</p> <p>Patient must be experiencing residual moderate to severe ADHD symptoms resulting in impaired functioning (social, academic or occupational), present in at least one setting (home, nursery/school/college/work, friends or family homes or other environment);</p> <p>Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.</p> | |
| C8555 | P8555 | CN8555 | Ipilimumab | <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Induction treatment</p> <p>The condition must not have previously been treated; AND</p> <p>The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.</p> <p>Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8555 |
| C8585 | P8585 | CN8585 | Guanfacine | <p>Attention deficit hyperactivity disorder</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine).</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8585 |
| C8588 | P8588 | CN8588 | Axitinib | <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Initial treatment</p> <p>Patient must have progressive disease according to the Response</p> | Compliance with Authority Required |

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| | | | | <p>Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p> | procedures |
| C8606 | P8606 | CN8606 | Tiotropium | <p>Severe asthma</p> <p>Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists; AND</p> <p>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</p> <p>Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; or</p> <p>Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>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;</p> <p>Patient must be aged 6 to 17 years inclusive.</p> <p>Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative</p> | Compliance with Authority Required procedures - Streamlined Authority Code 8606 |

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| C8621 | P8621 | CN8621 | Sorafenib | <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Initial treatment</p> <p>Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p> | Compliance with Authority Required procedures |
| C8622 | P8622 | CN8622 | Everolimus | <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Initial treatment</p> <p>Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.</p> <p>Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.</p> | Compliance with Authority Required procedures |
| C8624 | P8624 | CN8624 | Safinamide | <p>Parkinson disease</p> <p>The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.</p> | |
| C8667 | P8667 | CN8667 | Filgrastim | <p>Chemotherapy-induced neutropenia</p> <p>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND</p> | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | Patient must have had a prior episode of febrile neutropenia. or Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Code 8667 |
| C8668 | P8668 | CN8668 | Filgrastim | Mobilisation of peripheral blood progenitor cells The treatment must be in a normal volunteer for use in allogeneic transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 8668 |
| C8669 | P8669 | CN8669 | Filgrastim | Severe congenital neutropenia Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; AND Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage. | Compliance with Authority Required procedures - Streamlined Authority Code 8669 |
| C8670 | P8670 | CN8670 | Filgrastim | Severe chronic neutropenia Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; or Patient must have neutrophil dysfunction; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months. or Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 8670 |
| C8671 | P8671 | CN8671 | Filgrastim | Assisting bone marrow transplantation Patient must be receiving marrow-ablative chemotherapy prior to the transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 8671 |
| C8672 | P8672 | CN8672 | Filgrastim | Mobilisation of peripheral blood progenitor cells | Compliance with |

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| | | | | The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy. | Authority Required procedures - Streamlined Authority Code 8672 |
| C8673 | P8673 | CN8673 | Filgrastim | Chronic cyclical neutropenia Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles; AND Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics. or Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months. | Compliance with Authority Required procedures - Streamlined Authority Code 8673 |
| C8674 | P8674 | CN8674 | Filgrastim | Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia. or Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 8674 |
| C8696 | P8696 | CN8696 | Filgrastim | Assisting autologous peripheral blood progenitor cell transplantation The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 8696 |
| C8734 | P8734 | CN8734 | Adrenaline (epinephrine) | Acute allergic reaction with anaphylaxis Initial sole PBS-subsidised supply for anticipated emergency treatment Patient must have been discharged from hospital or an emergency department after treatment with adrenaline (epinephrine) for acute allergic reaction with anaphylaxis. | Compliance with Authority Required procedures |
| C8738 | P8738 | CN8738 | Riluzole | Amyotrophic lateral sclerosis Continuing treatment | Compliance with Authority Required |

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| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must be ambulatory; or Patient must not be ambulatory, and must be able to either use upper limbs or to swallow; AND Patient must not have undergone a tracheostomy; AND Patient must not have experienced respiratory failure. | procedures |
| C8774 | P8774 | CN8774 | Esomeprazole Lansoprazole Omeprazole Pantoprazole Rabeprazole | Gastro-oesophageal reflux disease The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease. or The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease. | Compliance with Authority Required procedures - Streamlined Authority Code 8774 |
| C8775 | P8775 | CN8775 | Esomeprazole Lansoprazole Omeprazole Pantoprazole Rabeprazole | Peptic ulcer Initial treatment Patient must have tested negative for helicobacter pylori infection. or Patient must have failed treatment with helicobacter pylori eradication therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 8775 |
| C8776 | P8776 | CN8776 | Esomeprazole Lansoprazole Omeprazole Pantoprazole Rabeprazole | Gastro-oesophageal reflux disease The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 8776 |
| C8780 | P8780 | CN8780 | Esomeprazole | Scleroderma oesophagus | Compliance with |

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| | | | Lansoprazole Omeprazole Pantoprazole Rabeprazole | | Authority Required procedures - Streamlined Authority Code 8780 |
| C8822 | P8822 | CN8822 | Botulinum toxin type A purified neurotoxin complex Clostridium botulinum type A toxin - haemagglutinin complex | Dynamic equinus foot deformity The condition must be due to spasticity; AND Patient must have cerebral palsy; AND Patient must be ambulant; Patient must be aged 18 years or older; Must be treated by a neurologist. or Must be treated by an orthopaedic surgeon. or Must be treated by a paediatrician. or Must be treated by a rehabilitation specialist. | Compliance with Authority Required procedures - Streamlined Authority Code 8822 |
| C8827 | P8827 | CN8827 | Esomeprazole | Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion | Compliance with Authority Required procedures - Streamlined Authority Code 8827 |
| C8830 | P8830 | CN8830 | Ixekizumab Secukinumab | Severe chronic plaque psoriasis Continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction; | Compliance with Written Authority Required procedures |

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| | | | | <p>Patient must be aged 18 years or older; Must be treated by a dermatologist. An adequate response to treatment is defined as A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application</p> | |

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| | | | | under a new cycle under the Initial 3 treatment restriction. | |
| C8831 | P8831 | CN8831 | Secukinumab | <p>Severe chronic plaque psoriasis</p> <p>Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND</p> | Compliance with Authority Required procedures |

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| | | | | Must be treated by a dermatologist. | |
| C8866 | P8866 | CN8866 | Omeprazole Pantoprazole | Zollinger-Ellison syndrome | Compliance with Authority Required procedures - Streamlined Authority Code 8866 |
| C8877 | P8877 | CN8877 | Guselkumab | Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 20 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 20 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment | Compliance with Authority Required procedures |

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| | | | | <p>after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions; AND</p> <p>Must be treated by a dermatologist.</p> | |
| C8892 | P8892 | CN8892 | Ixekizumab Secukinumab | <p>Severe chronic plaque psoriasis</p> <p>Continuing treatment, Face, hand, foot</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;</p> <p>Patient must be aged 18 years or older;</p> <p>Must be treated by a dermatologist.</p> <p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing</p> <p>(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</p> <p>(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.</p> <p>The authority application must be made in writing and must include</p> <p>(a) a completed authority prescription form(s); and</p> <p>(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</p> | Compliance with Written Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

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| | | | | <p>diagrams including the date of the assessment of the patient's condition.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.</p> <p>It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>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.</p> <p>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.</p> | |
| C8902 | P8902 | CN8902 | Esomeprazole | Gastro-oesophageal reflux disease Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor. | Compliance with Authority Required procedures |
| C8921 | P8921 | CN8921 | Febuxostat | Chronic gout The condition must be either chronic gouty arthritis or chronic tophaceous gout; AND Patient must have a medical contraindication to allopurinol. or Patient must have a documented history of allopurinol hypersensitivity | Compliance with Authority Required procedures - Streamlined Authority Code 8921 |

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| | | | | syndrome. or Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation. | |
| C8929 | P8929 | CN8929 | Botulinum toxin type A purified neurotoxin complex Clostridium botulinum type A toxin - haemagglutinin complex | Moderate to severe spasticity of the upper limb Patient must have cerebral palsy; Patient must be aged 18 years or older; Must be treated by a neurologist. or Must be treated by an orthopaedic surgeon. or Must be treated by a paediatrician. or Must be treated by a rehabilitation specialist. or Must be treated by a plastic surgeon. | Compliance with Authority Required procedures - Streamlined Authority Code 8929 |
| C9031 | P9031 | CN9031 | Guanfacine | Attention deficit hyperactivity disorder Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information. or Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal. or Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent. or Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously). | Compliance with Authority Required procedures - Streamlined Authority Code 9031 |
| C9034 | P9034 | CN9034 | Guanfacine | Attention deficit hyperactivity disorder Initial treatment Must be treated by a paediatrician or psychiatrist; AND | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

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| | | | | <p>The condition must be or have been diagnosed according to the DSM-5 criteria; AND</p> <p>Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; or</p> <p>Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine treatment and is of a severity necessitating treatment withdrawal; or</p> <p>Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; or</p> <p>Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously);</p> <p>Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.</p> | Code 9034 |
| C9063 | P9063 | CN9063 | Certolizumab pegol Golimumab Secukinumab | <p>Severe psoriatic arthritis</p> <p>Continuing treatment - balance of supply</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> | Compliance with Authority Required procedures |
| C9064 | P9064 | CN9064 | Adalimumab Bimekizumab Etanercept | <p>Severe psoriatic arthritis</p> <p>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</p> <p>Patient must have received insufficient therapy with this drug for this</p> | Compliance with Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| | | | Golimumab Secukinumab Tofacitinib Upadacitinib | <p>condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> | |
| C9069 | P9069 | CN9069 | Golimumab Secukinumab | <p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>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</p> | Compliance with Written Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older.</p> <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of</p> | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------------|--|---|
| | | | | <p>completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> | |
| C9073 | P9073 | CN9073 | Certolizumab pegol | <p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>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</p> <p>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</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;</p> <p>Patient must be aged 18 years or older;</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> <p>An adequate response to treatment is defined as</p> | Compliance with Written Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

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| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>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</p> <p>either of the following</p> <p>(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</p> <p>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised</p> | |

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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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| | | | | <p>treatment.</p> <p>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.</p> <p>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.</p> <p>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.</p> | |
| C9074 | P9074 | CN9074 | Certolizumab pegol | <p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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</p> <p>The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or</p> <p>The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND</p> <p>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</p> <p>Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;</p> <p>Patient must be aged 18 years or older.</p> | Compliance with Written Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations

Part 1 Circumstances, purposes and conditions

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|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>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).</p> <p>All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.</p> <p>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.</p> <p>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.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with</p> | |

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| | | | | <p>this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> | |
| C9081 | P9081 | CN9081 | Etanercept | <p>Severe psoriatic arthritis</p> <p>Continuing treatment - balance of supply</p> <p>Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> | Compliance with Authority Required procedures |
| C9105 | P9105 | CN9105 | <p>Certolizumab pegol</p> <p>Golimumab</p> <p>Secukinumab</p> | <p>Severe psoriatic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> | Compliance with Written Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

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| | | | | <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following</p> <p>(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</p> <p>(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> | |

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| | | | | <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>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.</p> | |
| C9155 | P9155 | CN9155 | Golimumab Secukinumab | <p>Severe psoriatic arthritis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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</p> <p>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</p> <p>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</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> | Compliance with Written Authority Required procedures |

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Part 1 Circumstances, purposes and conditions

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| | | | | <p>Patient must be aged 18 years or older.</p> <p>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.</p> <p>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.</p> <p>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</p> <p>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</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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</p> | |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------------------|--|---|
| | | | | <p>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.</p> <p>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.</p> <p>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.</p> | |
| C9172 | P9172 | CN9172 | Guselkumab Ixekizumab | <p>Severe psoriatic arthritis</p> <p>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</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; or</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.</p> | Compliance with Authority Required procedures |
| C9180 | P9180 | CN9180 | Tocilizumab | Active giant cell arteritis | Compliance with |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------------|--|---|
| | | | | Continuing treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 52 weeks in total including initial and continuing applications. | Authority Required procedures |
| C9183 | P9183 | CN9183 | Certolizumab pegol | Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction; Patient must be aged 18 years or older; Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>application</p> <p>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</p> <p>either</p> <p>(a) an active joint count of at least 20 active (swollen and tender) joints; or</p> <p>(b) at least 4 active joints from the following list of major joints</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>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.</p> <p>The authority application must be made in writing and must include</p> <p>(1) a completed authority prescription form(s); and</p> <p>(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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.</p> <p>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.</p> | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------------|--|---|
| C9185 | P9185 | CN9185 | Certolizumab pegol | <p>Severe psoriatic arthritis</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</p> | Compliance with Authority Required procedures |
| C9204 | P9204 | CN9204 | Imatinib | <p>Aggressive systemic mastocytosis with eosinophilia</p> <p>Initial treatment</p> <p>Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene; AND</p> <p>Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; or</p> <p>Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea); AND</p> <p>The treatment must not exceed a maximum dose of 400 mg per day.</p> <p>A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report</p> | 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) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.</p> <p>The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.</p> | |
| C9206 | P9206 | CN9206 | Imatinib | <p>Aggressive systemic mastocytosis with eosinophilia</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have confirmed evidence of carrying the FIP1L1-PDGfra fusion gene; AND</p> <p>Patient must have achieved and maintained a complete haematological response; AND</p> <p>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a maximum dose of 400 mg per day.</p> <p>A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9206 |
| C9209 | P9209 | CN9209 | Imatinib | <p>Dermatofibrosarcoma protuberans</p> <p>Continuing treatment</p> <p>The condition must be unresectable; or</p> <p>The condition must be locally recurrent; or</p> <p>The condition must be metastatic; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have demonstrated a response to the PBS-subsidised treatment; AND</p> <p>The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9209 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------------------------|--|---|
| | | | | The treatment must not exceed a maximum dose of 800 mg per day. Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records. | |
| C9216 | P9216 | CN9216 | Nivolumab | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Initial treatment Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor for this condition. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 9216 |
| C9222 | P9222 | CN9222 | Deferasirox | Chronic iron overload Continuing treatment Patient must not be transfusion dependent; AND The condition must be thalassaemia; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 9222 |
| C9223 | P9223 | CN9223 | Doxorubicin - pegylated liposomal | Kaposi sarcoma The condition must be AIDS-related; AND Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND The condition must include extensive visceral involvement. | Compliance with Authority Required procedures - Streamlined Authority Code 9223 |
| C9224 | P9224 | CN9224 | Lipegfilgrastim | Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a | Compliance with Authority Required |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | cure or a substantial remission; AND Patient must be at greater than 20% risk of developing febrile neutropenia. or Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days. | procedures - Streamlined Authority Code 9224 |
| C9228 | P9228 | CN9228 | Deferiprone | Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective. | Compliance with Authority Required procedures - Streamlined Authority Code 9228 |
| C9232 | P9232 | CN9232 | Octreotide | Vasoactive intestinal peptide secreting tumour (VIPoma) The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 9232 |
| C9233 | P9233 | CN9233 | Octreotide | Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; or The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or The treatment must be in a patient who is unfit for or unwilling to undergo | Compliance with Authority Required procedures - Streamlined Authority Code 9233 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------|---|---|
| | | | | <p>surgery and where radiotherapy is contraindicated; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks; AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.</p> <p>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission</p> | |
| C9234 | P9234 | CN9234 | Pamidronic acid | <p>Hypercalcaemia of malignancy</p> <p>Patient must have a malignancy refractory to anti-neoplastic therapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9234 |
| C9235 | P9235 | CN9235 | Pegfilgrastim | <p>Chemotherapy-induced neutropenia</p> <p>Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND</p> <p>Patient must be at greater than 20% risk of developing febrile neutropenia. or</p> <p>Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9235 |
| C9238 | P9238 | CN9238 | Imatinib | <p>Gastrointestinal stromal tumour</p> <p>Initial treatment</p> <p>The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST); AND</p> <p>Patient must be at high risk of recurrence following complete surgical resection of primary GIST; AND</p> <p>The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining; AND</p> <p>The treatment must not exceed a dose of 400 mg per day for a period of 36</p> | 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) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>months in total (initial plus continuing therapy). High risk of recurrence is defined as Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or Primary GIST greater than 10 cm with any mitotic rate; or Primary GIST with a mitotic count of greater than 10/50 HPF. 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. The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient's medical records.</p> | |
| C9240 | P9240 | CN9240 | Imatinib | <p>Dermatofibrosarcoma protuberans Initial treatment The condition must be unresectable; or The condition must be locally recurrent; or The condition must be metastatic; AND The treatment must not exceed a maximum dose of 800 mg per day. Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.</p> | Compliance with Authority Required procedures |
| C9243 | P9243 | CN9243 | Imatinib | <p>Myelodysplastic or myeloproliferative disorder Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must be PDGFRB fusion gene-positive; AND Patient must have achieved and maintained a complete haematological response; AND The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9243 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | The treatment must not exceed a maximum dose of 400 mg per day. A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records. | |
| C9247 | P9247 | CN9247 | Pazopanib | Advanced (unresectable and/or metastatic) soft tissue sarcoma Initial treatment Patient must have a WHO performance status of 2 or less; AND Patient must have received prior chemotherapy treatment including an anthracycline; AND Patient must not have received prior treatment with an angiogenesis inhibitor; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must not have any of the following conditions adipocytic soft tissue sarcoma; gastrointestinal stromal tumour (GIST); rhabdomyosarcoma other than alveolar or pleomorphic; chondrosarcoma; osteosarcoma; Ewings tumour/primitive neuroectodermal tumour; dermofibromatosis sarcoma protuberans; inflammatory myofibroblastic sarcoma; malignant mesothelioma; mixed mesodermal tumour of the uterus. | Compliance with Authority Required procedures - Streamlined Authority Code 9247 |
| C9248 | P9248 | CN9248 | Morphine | Chronic Breathlessness Patient must be receiving palliative care. | |
| C9252 | P9252 | CN9252 | Nivolumab | Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx Continuing treatment Patient must have previously received PBS-subsidised treatment with this | Compliance with Authority Required procedures - Streamlined Authority |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | drug for this condition; AND Patient must have stable or responding disease; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Code 9252 |
| C9258 | P9258 | CN9258 | Deferasirox | Chronic iron overload Continuing treatment Patient must be red blood cell transfusion dependent; AND Patient must have a malignant disorder of haemopoiesis; AND Patient must have previously received PBS-subsidised therapy with deferasirox for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 9258 |
| C9260 | P9260 | CN9260 | Lanreotide | Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 9260 |
| C9261 | P9261 | CN9261 | Lanreotide | Acromegaly The condition must be active; AND Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre; AND The treatment must be after failure of other therapy including dopamine agonists; or | Compliance with Authority Required procedures - Streamlined Authority Code 9261 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

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|--------------------|---------------|-----------------|--------------|---|---|
| | | | | <p>The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</p> <p>The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised pegvisomant.</p> <p>In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.</p> | |
| C9262 | P9262 | CN9262 | Octreotide | <p>Acromegaly</p> <p>The condition must be controlled with octreotide immediate release injections; AND</p> <p>The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose); AND</p> <p>The treatment must cease if IGF1 is not lower after 3 months of treatment; AND</p> <p>The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.</p> <p>In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9262 |
| C9267 | P9267 | CN9267 | Valaciclovir | <p>Cytomegalovirus infection and disease</p> <p>Prophylaxis</p> <p>Patient must have undergone a renal transplant; AND</p> <p>Patient must be at risk of cytomegalovirus disease.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9267 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------|--|---|
| C9268 | P9268 | CN9268 | Zoledronic acid | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 9268 |
| C9274 | P9274 | CN9274 | Imatinib | Chronic eosinophilic leukaemia or Hypereosinophilic syndrome Initial treatment Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene; AND The treatment must not exceed a maximum dose of 400 mg per day. A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C9276 | P9276 | CN9276 | Imatinib | Myelodysplastic or myeloproliferative disorder Initial treatment Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; or Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); or Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript; AND Patient must have previously failed an adequate trial of conventional therapy with cytarabine; or Patient must have previously failed an adequate trial of conventional therapy with etoposide; or Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea); AND | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------------------------|--|---|
| | | | | <p>The treatment must not exceed a maximum dose of 400 mg per day.</p> <p>A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.</p> | |
| C9278 | P9278 | CN9278 | Imatinib | <p>Gastrointestinal stromal tumour</p> <p>Continuing treatment</p> <p>The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST); AND</p> <p>Patient must be at high risk of recurrence following complete surgical resection of primary GIST; AND</p> <p>The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy); AND</p> <p>Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9278 |
| C9286 | P9286 | CN9286 | Deferiprone | <p>Iron overload</p> <p>Patient must have thalassaemia major; AND</p> <p>Patient must be unable to take desferrioxamine therapy.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9286 |
| C9287 | P9287 | CN9287 | Doxorubicin - pegylated liposomal | <p>Kaposi sarcoma</p> <p>The condition must be AIDS-related; AND</p> <p>Patient must have a CD4 cell count of less than 200 per cubic millimetre; AND</p> <p>The condition must include extensive mucocutaneous involvement.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9287 |
| C9288 | P9288 | CN9288 | Octreotide | <p>Vasoactive intestinal peptide secreting tumour (VIPoma)</p> <p>Patient must have achieved symptom control on octreotide immediate release injections; AND</p> <p>The treatment must cease if there is failure to produce a clinically significant</p> | Compliance with Authority Required procedures - Streamlined Authority |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Code 9288 |
| C9289 | P9289 | CN9289 | Octreotide | Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Compliance with Authority Required procedures - Streamlined Authority Code 9289 |
| C9290 | P9290 | CN9290 | Thalidomide | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 9290 |
| C9296 | P9296 | CN9296 | Imatinib | Chronic eosinophilic leukaemia or Hypereosinophilic syndrome Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved and maintained a complete haematological response; AND The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND | Compliance with Authority Required procedures - Streamlined Authority Code 9296 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>The treatment must not exceed a maximum dose of 400 mg per day.</p> <p>A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.</p> | |
| C9298 | P9298 | CN9298 | Nivolumab | <p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Continuing treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have previously been issued with an authority prescription for this drug for this condition; AND</p> <p>Patient must have stable or responding disease.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9298 |
| C9299 | P9299 | CN9299 | Nivolumab | <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9299 |
| C9302 | P9302 | CN9302 | Deferasirox | <p>Chronic iron overload</p> <p>Continuing treatment</p> <p>Patient must be transfusion dependent; AND</p> <p>Patient must not have a malignant disorder of erythropoiesis; AND</p> <p>Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9302 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------|---|---|
| C9303 | P9303 | CN9303 | Pegfilgrastim | Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia. or Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 9303 |
| C9304 | P9304 | CN9304 | Zoledronic acid | Bone metastases The condition must be due to castration-resistant prostate cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 9304 |
| C9312 | P9312 | CN9312 | Nivolumab | Stage IV clear cell variant renal cell carcinoma (RCC) Initial Treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; or Patient must have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 9312 |
| C9313 | P9313 | CN9313 | Octreotide | Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate | Compliance with Authority Required procedures - |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------|--|---|
| | | | | release injections; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose. | Streamlined Authority Code 9313 |
| C9315 | P9315 | CN9315 | Pamidronic acid | Bone metastases The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 9315 |
| C9317 | P9317 | CN9317 | Zoledronic acid | Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 9317 |
| C9319 | P9319 | CN9319 | Imatinib | Malignant gastrointestinal stromal tumour Initial Treatment The condition must be metastatic; or The condition must be unresectable; AND The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining; AND The treatment must be commenced at a dose not exceeding 400 mg per day; AND The treatment must not exceed 3 months under this restriction. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period. Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this | 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) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>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.</p> <p>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.)</p> <p>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.</p> <p>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.</p> <p>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.</p> | |
| C9321 | P9321 | CN9321 | Nivolumab | <p>Stage IV clear cell variant renal cell carcinoma (RCC)</p> <p>Maintenance treatment</p> <p>Patient must have previously received of up to maximum 4 doses of PBS-subsidised combined therapy with nivolumab and ipilimumab as induction for this condition; AND</p> <p>The treatment must be as monotherapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p> <p>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.</p> <p>The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9321 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|---|--|---|
| C9322 | P9322 | CN9322 | Lipegfilgrastim | Chemotherapy-induced neutropenia Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission; AND Patient must have had a prior episode of febrile neutropenia. or Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days. | Compliance with Authority Required procedures - Streamlined Authority Code 9322 |
| C9328 | P9328 | CN9328 | Zoledronic acid | Bone metastases The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 9328 |
| C9329 | P9329 | CN9329 | Plerixafor | Mobilisation of haematopoietic stem cells The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF); AND Patient must have lymphoma; or Patient must have multiple myeloma; AND Patient must require autologous stem cell transplantation; AND Patient must have failed previous stem cell collection. or Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection. or Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg. Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9329 |
| C9334 | P9334 | CN9334 | Botulinum toxin type A purified neurotoxin complex Clostridium botulinum type A toxin - haemagglutinin complex | Moderate to severe spasticity of the lower limb following an acute event Must be treated by a neurologist; or Must be treated by an orthopaedic surgeon; or Must be treated by a rehabilitation specialist; or Must be treated by a plastic surgeon; or | Compliance with Authority Required procedures - Streamlined Authority Code 9334 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------|---|---|
| | | | | <p>Must be treated by a geriatrician; AND</p> <p>The condition must be moderate to severe spasticity of the lower limb/s following stroke or other acute neurological event, defined as a Modified Ashworth Scale rating of 3 or more; AND</p> <p>The treatment must only be used as second line therapy when standard management has failed; or</p> <p>The treatment must only be used as an adjunct to physical therapy; AND</p> <p>The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating of at least 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND</p> <p>Patient must not have established severe contracture in the limb to be treated; AND</p> <p>The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per lower limb in the the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per lower limb each year thereafter;</p> <p>Patient must be aged 18 years or older.</p> <p>Standard management includes physiotherapy and/or oral spasticity agents.</p> | |
| C9335 | P9335 | CN9335 | Pamidronic acid | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 9335 |
| C9349 | P9349 | CN9349 | Trastuzumab | <p>Metastatic (Stage IV) HER2 positive breast cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>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.</p> <p>Where a patient has a break in trastuzumab therapy of more than 1 week</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9349 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--------------|--|---|
| | | | | from when the last dose was due, a new loading dose may be required. | |
| C9353 | P9353 | CN9353 | Trastuzumab | <p>Metastatic (Stage IV) HER2 positive breast cancer</p> <p>Initial treatment</p> <p>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; AND</p> <p>The treatment must not be in combination with nab-paclitaxel; AND</p> <p>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.</p> <p>Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9353 |
| C9360 | P9360 | CN9360 | Lapatinib | <p>Metastatic (Stage IV) HER2 positive breast cancer</p> <p>Continuing treatment</p> <p>Patient must have received an initial authority prescription for this drug for this condition; AND</p> <p>The treatment must be in combination with capecitabine; AND</p> <p>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition; AND</p> <p>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.</p> <p>A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.</p> <p>The treatment must not exceed a lifetime total of one continuous course.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9360 |
| C9369 | P9369 | CN9369 | Blinatumomab | <p>Acute lymphoblastic leukaemia</p> <p>Consolidation treatment</p> <p>Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND</p> | 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) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | <p>Patient must have achieved a complete remission; or</p> <p>Patient must have achieved a complete remission with partial haematological recovery; AND</p> <p>The treatment must not be more than 3 treatment cycles under this restriction in a lifetime; AND</p> <p>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.</p> | |
| C9380 | P9380 | CN9380 | Tocilizumab | <p>Severe active juvenile idiopathic arthritis</p> <p>Continuing Treatment - balance of supply</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.</p> | Compliance with Authority Required procedures |
| C9386 | P9386 | CN9386 | <p>Adalimumab</p> <p>Etanercept</p> <p>Tocilizumab</p> | <p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>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</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete</p> | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | |
| C9391 | P9391 | CN9391 | Tocilizumab | Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; or Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction; Patient must be aged 18 years or older. Active joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/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) |
|--------------------|---------------|-----------------|--------------------------------------|---|---|
| | | | | <p>(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).</p> <p>All measures of joint count must be no more than 4 weeks old at the time of this application.</p> <p>The authority application must be made in writing and must include</p> <p>(1) completed authority prescription form(s); and</p> <p>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>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.</p> | |
| C9417 | P9417 | CN9417 | <p>Etanercept</p> <p>Tofacitinib</p> | <p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - 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</p> | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | biological medicine of more than 12 months) - balance of supply Must be treated by a paediatric rheumatologist; or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | |
| C9429 | P9429 | CN9429 | Golimumab Ixekizumab Secukinumab | Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks | 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) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | <p>treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> | |
| C9431 | P9431 | CN9431 | <p>Certolizumab pegol</p> <p>Golimumab</p> <p>Ixekizumab</p> <p>Secukinumab</p> <p>Tofacitinib</p> <p>Upadacitinib</p> | <p>Ankylosing spondylitis</p> <p>Continuing treatment - balance of supply</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> | Compliance with Authority Required procedures |
| C9462 | P9462 | CN9462 | Trastuzumab | <p>Metastatic (Stage IV) HER2 positive breast cancer</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>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.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9462 |
| C9465 | P9465 | CN9465 | Ponatinib | <p>Acute lymphoblastic leukaemia</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.</p> | Compliance with Authority Required procedures |
| C9470 | P9470 | CN9470 | Inotuzumab ozogamicin | <p>Acute lymphoblastic leukaemia</p> <p>Induction treatment</p> <p>The condition must be relapsed or refractory B-precursor cell ALL, with an</p> | Compliance with Written Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND Patient must not have received more than 1 line of salvage therapy; AND Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND The condition must be CD22-positive; AND The condition must have more than 5% blasts in bone marrow; AND The treatment must not be more than 3 treatment cycles under this restriction in a lifetime. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include (1) two completed authority prescription forms; (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) evidence that the condition is CD22-positive; and (4) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and (5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application. The treatment must not exceed 0.8mg per m ² for the first dose of a treatment cycle (Day 1), and 0.5mg per m ² for subsequent doses (Days 8 and 15) within a treatment cycle. Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime. | Required procedures |
| C9477 | P9477 | CN9477 | Tocilizumab | Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less | 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) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply</p> <p>Must be treated by a paediatric rheumatologist; or</p> <p>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND</p> <p>Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment; AND</p> <p>The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions for patients 30 kg or over.</p> <p>or</p> <p>The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.</p> | |
| C9478 | P9478 | CN9478 | Tocilizumab | <p>Severe active juvenile idiopathic arthritis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> <p>Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current</p> | Compliance with Written Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>treatment cycle; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction;</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as</p> <p>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;</p> <p>AND either of the following</p> <p>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or</p> <p>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or</p> <p>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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).</p> <p>The authority application must be made in writing and must include</p> <p>(1) completed authority prescription form(s); and</p> <p>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>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.</p> <p>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</p> | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> | |
| C9488 | P9488 | CN9488 | Baclofen | <p>Severe chronic spasticity</p> <p>Patient must have failed to respond to treatment with oral antispastic agents; or</p> <p>Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND</p> <p>Patient must have chronic spasticity of cerebral origin.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9488 |
| C9489 | P9489 | CN9489 | Baclofen | Severe chronic spasticity | Compliance with Authority Required |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

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|--------------------|---------------|-----------------|--------------|---|---|
| | | | | <p>Patient must have failed to respond to treatment with oral antispastic agents; or</p> <p>Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND</p> <p>Patient must have chronic spasticity due to spinal cord injury.</p> | procedures - Streamlined Authority Code 9489 |
| C9490 | P9490 | CN9490 | Clozapine | <p>Schizophrenia</p> <p>Initial treatment</p> <p>Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient; AND</p> <p>Patient must be non-responsive to other neuroleptic agents. or</p> <p>Patient must be intolerant of other neuroleptic agents.</p> <p>Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.</p> <p>The name of the consulting psychiatrist should be included in the patient's medical records.</p> <p>A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9490 |
| C9519 | P9519 | CN9519 | Blinatumomab | <p>Acute lymphoblastic leukaemia</p> <p>Induction treatment - balance of supply</p> <p>The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND</p> <p>The condition must not be present in the central nervous system or testis; AND</p> <p>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND</p> <p>Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime.</p> <p>According to the TGA-approved Product Information, hospitalisation is</p> | Compliance with Authority Required procedures |

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| | | | | recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended. An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. | |
| C9523 | P9523 | CN9523 | Ocrelizumab | Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND Patient must be ambulatory (without assistance or support); AND Must be treated by a neurologist. Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9523 |
| C9524 | P9524 | CN9524 | Baclofen | Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; or Patient must have had unacceptable side effects to treatment with oral | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

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|--------------------|---------------|-----------------|-------------|---|---|
| | | | | antispastic agents; AND Patient must have chronic spasticity due to spinal cord disease. | Code 9524 |
| C9525 | P9525 | CN9525 | Baclofen | Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; or Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis. | Compliance with Authority Required procedures - Streamlined Authority Code 9525 |
| C9527 | P9527 | CN9527 | Mannitol | Cystic fibrosis The treatment must be as monotherapy; AND Patient must be intolerant or inadequately responsive to dornase alfa; Patient must be 6 years of age or older. Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. | Compliance with Authority Required procedures - Streamlined Authority Code 9527 |

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| | | | | Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | |
| C9547 | P9547 | CN9547 | Botulinum toxin type A purified neurotoxin complex Clostridium botulinum type A toxin - haemagglutinin complex IncobotulinumtoxinA | Moderate to severe spasticity of the upper limb following an acute event The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more; AND The treatment must only be used as second line therapy when standard management has failed; or The treatment must only be used as an adjunct to physical therapy; AND The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter; AND Patient must not have established severe contracture in the limb to be treated; Patient must be aged 18 years or older; Must be treated by a neurologist. or Must be treated by an orthopaedic surgeon. or Must be treated by a rehabilitation specialist. or Must be treated by a plastic surgeon. or Must be treated by a geriatrician. Standard management includes physiotherapy and/or oral spasticity agents. | Compliance with Authority Required procedures - Streamlined Authority Code 9547 |
| C9549 | P9549 | CN9549 | Dasatinib | Acute lymphoblastic leukaemia Continuing treatment The condition must be expressing the Philadelphia chromosome; or | Compliance with Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

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| | | | | <p>The condition must have the transcript BCR-ABL; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy following treatment with imatinib; AND</p> <p>The condition must not have progressed.</p> | |
| C9553 | P9553 | CN9553 | Tocilizumab | <p>Severe active juvenile idiopathic arthritis</p> <p>Continuing treatment</p> <p>Must be treated by a rheumatologist; or</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND</p> <p>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as</p> <p>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;</p> <p>AND either of the following</p> <p>(a) an active joint count of fewer than 10 active (swollen and tender) joints; or</p> <p>(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or</p> <p>(c) a reduction in the number of the following active joints, from at least 4, by at least 50%</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(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</p> | Compliance with Written Authority Required procedures |

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|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>joint destruction or bony overgrowth).</p> <p>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.</p> <p>The authority application must be made in writing and must include</p> <p>(1) completed authority prescription form(s); and</p> <p>(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>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.</p> <p>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</p> | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
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| | | | | under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | |
| C9560 | P9560 | CN9560 | Rifabutin | Mycobacterium avium complex infection Patient must be human immunodeficiency virus (HIV) positive. | Compliance with Authority Required procedures - Streamlined Authority Code 9560 |
| C9562 | P9562 | CN9562 | Baclofen | Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; or Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity of cerebral origin. | Compliance with Authority Required procedures - Streamlined Authority Code 9562 |
| C9571 | P9571 | CN9571 | Trastuzumab | Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. | Compliance with Authority Required procedures - Streamlined Authority Code 9571 |
| C9573 | P9573 | CN9573 | Trastuzumab | Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastro-oesophageal junction Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) positivity as demonstrated by immunohistochemistry 2+ or more in tumour material; AND Patient must have evidence of HER2 gene amplification as demonstrated by | Compliance with Authority Required procedures - Streamlined Authority Code 9573 |

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| | | | | <p>in situ hybridisation results based on more than 6 copies of HER2 in the same tumour tissue sample; AND</p> <p>Patient must have evidence of HER2 gene amplification as demonstrated by in situ hybridisation results based on the ratio of HER2 to chromosome 17 being more than 2 in the same tumour tissue sample; AND</p> <p>Patient must commence treatment in combination with platinum based chemotherapy and capecitabine; or</p> <p>Patient must commence treatment in combination with platinum based chemotherapy and 5 fluorouracil; AND</p> <p>Patient must not have previously received this drug for this condition; AND</p> <p>Patient must not have received prior chemotherapy for this condition; AND</p> <p>Patient must have a WHO performance status of 2 or less; AND</p> <p>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.</p> <p>Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.</p> | |
| C9589 | P9589 | CN9589 | Alemtuzumab | <p>Multiple sclerosis</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not show continuing progression of disability while on treatment with this drug; AND</p> <p>Patient must not receive more than one PBS-subsidised treatment per year; AND</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must have demonstrated compliance with, and an ability to tolerate this therapy; AND</p> <p>Must be treated by a neurologist.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9589 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

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| C9590 | P9590 | CN9590 | Deferiprone | Iron overload Patient must have thalassaemia major; AND Patient must be one in whom desferrioxamine therapy has proven ineffective. | Compliance with Authority Required procedures - Streamlined Authority Code 9590 |
| C9591 | P9591 | CN9591 | Dornase alfa | Cystic fibrosis Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; or Patient must have significant bronchiectasis on chest high resolution computed tomography scan; or Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; or Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy; Patient must be less than 5 years of age. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals. | Compliance with Authority Required procedures - Streamlined Authority Code 9591 |
| C9592 | P9592 | CN9592 | Dornase alfa | Cystic fibrosis Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years; AND | Compliance with Authority Required procedures - Streamlined Authority |

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| | | | | <p>Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit;</p> <p>Patient must be 5 years of age or older.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.</p> | Code 9592 |
| C9593 | P9593 | CN9593 | Mannitol | <p>Cystic fibrosis</p> <p>The treatment must be in combination with dornase alfa; AND</p> <p>Patient must be inadequately responsive to dornase alfa; AND</p> <p>Patient must have trialled hypertonic saline for this condition;</p> <p>Patient must be 6 years of age or older.</p> <p>Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.</p> <p>Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.</p> <p>Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.</p> <p>Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.</p> <p>To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment</p> <p>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND</p> <p>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.</p> <p>Further reassessments must be undertaken and documented at six-monthly</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9593 |

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| | | | | intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | |
| C9601 | P9601 | CN9601 | Inotuzumab ozogamicin | <p>Acute lymphoblastic leukaemia</p> <p>Consolidation treatment</p> <p>Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND</p> <p>Patient must have achieved a complete remission; or</p> <p>Patient must have achieved a complete remission with partial haematological recovery; AND</p> <p>The treatment must not be more than 5 treatment cycles under this restriction in a lifetime; AND</p> <p>Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.</p> <p>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The treatment must not exceed 0.5mg per m² for all doses within a treatment cycle</p> <p>Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.</p> | Compliance with Authority Required procedures |
| C9604 | P9604 | CN9604 | Azithromycin | <p>Mycobacterium avium complex infection</p> <p>The treatment must be for prophylaxis; AND</p> <p>Patient must be human immunodeficiency virus (HIV) positive; AND</p> <p>Patient must have CD4 cell counts of less than 75 per cubic millimetre.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9604 |
| C9606 | P9606 | CN9606 | Baclofen | <p>Severe chronic spasticity</p> <p>Patient must have failed to respond to treatment with oral antispastic agents; or</p> <p>Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9606 |

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| C9614 | P9614 | CN9614 | Ponatinib | <p>Patient must have chronic spasticity due to spinal cord disease.</p> <p>Acute lymphoblastic leukaemia</p> <p>Initial treatment</p> <p>The condition must be expressing the Philadelphia chromosome; or</p> <p>The condition must have the transcript BCR-ABL; AND</p> <p>Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition. or</p> <p>Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal.</p> <p>Failure of treatment with dasatinib is defined as either</p> <ol style="list-style-type: none"> 1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or 2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or 3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. <p>Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission; OR rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.</p> <p>The authority application must be made in writing and must include</p> <ol style="list-style-type: none"> 1. a completed authority prescription form; and 2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and 3. a pathology report demonstrating that the patient has active acute | Compliance with Written Authority Required procedures |

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| | | | | lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided; or 4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided | |
| C9622 | P9622 | CN9622 | Rifabutin | Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre. | Compliance with Authority Required procedures - Streamlined Authority Code 9622 |
| C9623 | P9623 | CN9623 | Deferiprone | Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 9623 |
| C9624 | P9624 | CN9624 | Dornase alfa | Cystic fibrosis Patient must be 5 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment | Compliance with Authority Required procedures - Streamlined Authority Code 9624 |

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| | | | | <p>(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND</p> <p>(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.</p> <p>Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.</p> | |
| C9625 | P9625 | CN9625 | Certolizumab pegol | <p>Ankylosing spondylitis</p> <p>Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply</p> <p>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</p> <p>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</p> <p>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</p> <p>The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions; AND</p> <p>Must be treated by a rheumatologist. or</p> <p>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.</p> | Compliance with Authority Required procedures |
| C9635 | P9635 | CN9635 | Ocrelizumab | <p>Multiple sclerosis</p> <p>Continuing treatment</p> | Compliance with Authority Required |

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|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not show continuing progression of disability while on treatment with this drug; AND</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>Patient must have demonstrated compliance with, and an ability to tolerate this therapy; AND</p> <p>Must be treated by a neurologist.</p> | procedures - Streamlined Authority Code 9635 |
| C9636 | P9636 | CN9636 | Alemtuzumab | <p>Multiple sclerosis</p> <p>Initial treatment</p> <p>The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; or</p> <p>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</p> <p>The treatment must be the sole PBS-subsidised disease modifying therapy for this condition; AND</p> <p>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</p> <p>Patient must be ambulatory (without assistance or support); AND</p> <p>Must be treated by a neurologist.</p> <p>Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9636 |
| C9637 | P9637 | CN9637 | Baclofen | <p>Severe chronic spasticity</p> <p>Patient must have failed to respond to treatment with oral antispastic agents; or</p> | Compliance with Authority Required procedures - Streamlined Authority |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|---|---|
| | | | | Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to multiple sclerosis. | Code 9637 |
| C9638 | P9638 | CN9638 | Baclofen | Severe chronic spasticity Patient must have failed to respond to treatment with oral antispastic agents; or Patient must have had unacceptable side effects to treatment with oral antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury. | Compliance with Authority Required procedures - Streamlined Authority Code 9638 |
| C9639 | P9639 | CN9639 | Interferon gamma-1b | Chronic granulomatous disease Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents. | Compliance with Authority Required procedures - Streamlined Authority Code 9639 |
| C9651 | P9651 | CN9651 | Golimumab | Moderate to severe ulcerative colitis Continuing treatment - balance of supply Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under this restriction. | Compliance with Authority Required procedures |
| C9688 | P9688 | CN9688 | Darbepoetin alfa Epoetin alfa Epoetin beta | Anaemia associated with intrinsic renal disease Patient must require transfusion; AND Patient must have a haemoglobin level of less than 100 g per L; AND Patient must have intrinsic renal disease, as assessed by a nephrologist. | Compliance with Authority Required procedures - Streamlined Authority |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | Epoetin lambda Methoxy polyethylene glycol-epoetin beta | | Code 9688 |
| C9694 | P9694 | CN9694 | Ciclosporin | Nephrotic syndrome Management (initiation, stabilisation and review of therapy) Patient must have failed prior treatment with steroids and cytostatic drugs; or Patient must be intolerant to treatment with steroids and cytostatic drugs; or The condition must be considered inappropriate for treatment with steroids and cytostatic drugs; AND Patient must not have renal impairment; AND Must be treated by a nephrologist. | Compliance with Authority Required procedures - Streamlined Authority Code 9694 |
| C9695 | P9695 | CN9695 | Ciclosporin | Severe atopic dermatitis Management (initiation, stabilisation and review of therapy) Must be treated by a dermatologist; or Must be treated by a clinical immunologist; AND The condition must be ineffective to other systemic therapies. or The condition must be inappropriate for other systemic therapies. | Compliance with Authority Required procedures - Streamlined Authority Code 9695 |
| C9696 | P9696 | CN9696 | Desferrioxamine | Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload. | Compliance with Authority Required procedures - Streamlined Authority Code 9696 |
| C9705 | P9705 | CN9705 | Golimumab | Moderate to severe ulcerative colitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or | Compliance with Written Authority Required procedures |

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND</p> <p>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</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p> <p>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);</p> <p>Patient must be aged 18 years or older.</p> <p>Application for authorisation must be made in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.</p> <p>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.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>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</p> | |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.</p> <p>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.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>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.</p> <p>Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p> | |
| C9742 | P9742 | CN9742 | Ciclosporin | <p>Severe active rheumatoid arthritis</p> <p>Management (initiation, stabilisation and review of therapy)</p> <p>The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); or</p> <p>The condition must be considered inappropriate for treatment with slow-</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9742 |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|--|--|---|
| | | | | acting anti-rheumatic agents (including methotrexate); AND Must be treated by a rheumatologist. or Must be treated by a clinical immunologist. | |
| C9745 | P9745 | CN9745 | Golimumab | Moderate to severe ulcerative colitis Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); or Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); or Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); AND The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment. | Compliance with Authority Required procedures |
| C9762 | P9762 | CN9762 | Lanthanum Sevelamer Sucroferric oxyhydroxide | Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; or | Compliance with Authority Required procedures - Streamlined Authority Code 9762 |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents; AND Patient must be undergoing dialysis for chronic kidney disease. | |
| C9764 | P9764 | CN9764 | Ciclosporin | Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9764 |
| C9770 | P9770 | CN9770 | Golimumab | Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; Patient must be aged 18 years or older. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. | 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) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.</p> <p>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.</p> | |
| C9822 | P9822 | CN9822 | Golimumab | <p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 1 (new patient)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>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</p> <p>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</p> <p>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</p> | Compliance with Written Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>consecutive months or have intolerance necessitating permanent treatment withdrawal; or</p> <p>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</p> <p>Patient must have a Mayo clinic score greater than or equal to 6; or</p> <p>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);</p> <p>Patient must be aged 18 years or older.</p> <p>Application for authorisation of initial treatment must be in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and</p> <p>(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].</p> <p>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.</p> <p>The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.</p> <p>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</p> | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|--|---|
| | | | | <p>adequate time for a response to be demonstrated.</p> <p>A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.</p> <p>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.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.</p> <p>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.</p> <p>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.</p> <p>Details of the accepted toxicities including severity can be found on the Department of Human Services website.</p> | |
| C9823 | P9823 | CN9823 | Golimumab | <p>Moderate to severe ulcerative colitis</p> <p>Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)</p> <p>Must be treated by a gastroenterologist (code 87); or</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND</p> <p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</p> | Compliance with Written Authority Required procedures |

Schedule 4 Circumstances, purposes, conditions and variations**Part 1** Circumstances, purposes and conditions

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-------------|---|---|
| | | | | <p>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;</p> <p>Patient must be aged 18 years or older.</p> <p>Application for authorisation must be made in writing and must include</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following</p> <p>(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</p> <p>(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.</p> <p>A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.</p> <p>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.</p> <p>Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.</p> <p>An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised</p> | |

Clause 1

| Circumstances Code | Purposes Code | Conditions Code | Listed Drug | Circumstances and Purposes | Authority Requirements (part of Circumstances; or Conditions) |
|--------------------|---------------|-----------------|-----------------------|---|---|
| | | | | <p>treatment.</p> <p>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.</p> <p>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.</p> <p>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.</p> | |
| C9828 | P9828 | CN9828 | Terbutaline | <p>Bronchospasm</p> <p>Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist. or</p> <p>Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.</p> <p>Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9828 |
| C9831 | P9831 | CN9831 | Ciclosporin | <p>Management of transplant rejection</p> <p>The treatment must be used by organ or tissue transplant recipients.</p> | Compliance with Authority Required procedures - Streamlined Authority Code 9831 |
| C9919 | P9919 | CN9919 | Sodium phenylbutyrate | <p>Urea cycle disorders</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition.</p> | Compliance with Authority Required procedures - Streamlined Authority |

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|--------------------|---------------|-----------------|---|---|---|
| | | | | | Code 9919 |
| C9981 | P9981 | CN9981 | Dolutegravir with abacavir and lamivudine | HIV infection Initial treatment Patient must be antiretroviral treatment naive. | Compliance with Authority Required procedures - Streamlined Authority Code 9981 |
| C9987 | P9987 | CN9987 | Dolutegravir with lamivudine | HIV infection Initial treatment Patient must be antiretroviral treatment naive; AND Patient must not have suspected resistance to either antiretroviral component. | Compliance with Authority Required procedures - Streamlined Authority Code 9987 |
| C9993 | P9993 | CN9993 | Sodium phenylbutyrate | Urea cycle disorders Initial treatment Patient must have elevated ammonia levels that are not controlled with diet alone and other adjunct care alone. | Compliance with Authority Required procedures - Streamlined Authority Code 9993 |