

**PB 26 of 2024**

National Health (Listing of Pharmaceutical Benefits) Instrument 2024

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

*National Health Act 1953*

This Instrument is in 8 volumes

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

Volume 2: Schedule 1 (Part 1: D–K)

Volume 3: Schedule 1 (Part 1: L–P)

Volume 4: Schedule 1 (Part 1: Q–Z, Part 2), Schedules 2 and 3

**Volume 5: Schedule 4 (Part 1: C4000–C9999)**

Volume 6: Schedule 4 (Part 1: C10000–C12999)

Volume 7: Schedule 4 (Part 1: C13000 onwards, Part 2)

Volume 8: Schedule 5, Schedule 6 and Endnotes

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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)** |
| --- | --- | --- | --- | --- | --- |
| C4072 | P4072 | CN4072 | Paraffin with retinol palmitate | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| 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. |  |
| C4084 | P4084 | CN4084 | Mycophenolic acid | Prophylaxis of renal allograft rejection  Management  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 4084 |
| 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 |
| C4095 | P4095 | CN4095 | Mycophenolic acid | WHO Class III, IV or V lupus nephritis  Management  The condition must be proven by biopsy; AND  Must be treated by a nephrologist or in consultation with a nephrologist.  The name of the consulting nephrologist must be included in the patient medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 4095 |
| 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 |
| C4105 | P4105 | CN4105 | Hyaluronic acid | Severe dry eye syndrome  Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 4105 |
| 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. |  |
| C4150 | P4150 | CN4150 | Denosumab | Bone metastases  The condition must be due to castration-resistant prostate cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 4150 |
| C4158 | P4158 | CN4158 | Denosumab | Bone metastases  The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 4158 |
| C4159 | P4159 | CN4159 | Naproxen | Chronic arthropathies (including osteoarthritis)  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. | Compliance with Authority Required 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 |
| C4190 | P4190 | CN4190 | Rotigotine | Parkinson disease  The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. |  |
| C4195 | P4195 | CN4195 | Ciprofloxacin  Ofloxacin | Bacterial keratitis  Must be treated by an ophthalmologist or in consultation with an ophthalmologist. | Compliance with Authority Required procedures |
| C4204 | P4204 | CN4204 | Rotigotine | Parkinson disease  The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. |  |
| C4211 | P4211 | CN4211 | Aprepitant | Nausea and vomiting  The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND  The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND  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.  No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 4211 |
| C4215 | P4215 | CN4215 | Aprepitant | 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 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 4215 |
| C4216 | P4216 | CN4216 | Aprepitant | 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 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 4216 |
| C4223 | P4223 | CN4223 | Aprepitant | Nausea and vomiting  The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND  The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND  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.  No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 4223 |
| C4229 | P4229 | CN4229 | Imiquimod | Superficial basal cell carcinoma  The condition must be previously untreated; AND  The condition must be confirmed by biopsy; AND  Patient must have normal immune function; AND  The condition must not be suitable for treatment with surgical excision; or  The condition must not be suitable for treatment with cryotherapy; or  The condition must not be suitable for treatment with curettage with diathermy; AND  Patient must require topical drug therapy.  The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application. | 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 - 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  Brexpiprazole  Cariprazine  Lurasidone  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. |  |
| C4260 | P4260 | CN4260 | Rivaroxaban | Pulmonary embolism  Initial treatment  Patient must have confirmed acute symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 4260 |
| C4268 | P4268 | CN4268 | Rivaroxaban | Pulmonary embolism  Continuing treatment  Patient must have confirmed acute symptomatic pulmonary embolism. | Compliance with 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 |
| C4274 | P4274 | CN4274 | Raltegravir | HIV infection  Continuing  The treatment must be in combination with other antiretroviral agents; AND  Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND  Patient must have previously received PBS-subsidised therapy for HIV infection;  Patient must be aged 2 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4274 |
| C4275 | P4275 | CN4275 | Raltegravir | HIV infection  Initial  The treatment must be in combination with other antiretroviral agents; AND  Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy; AND  Patient must have a CD4 count of less than 500 per cubic millimetre; or  Patient must have symptomatic HIV disease;  Patient must be aged 2 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4275 |
| 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 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 long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine  Tyrosine with carbohydrate | Phenylketonuria |  |
| C4302 | P4302 | CN4302 | Iron polymaltose complex  Iron sucrose | Iron deficiency anaemia  Patient must be undergoing chronic haemodialysis. | Compliance with Authority Required procedures - Streamlined Authority Code 4302 |
| C4304 | P4304 | CN4304 | Olanzapine | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 4304 |
| C4305 | P4305 | CN4305 | 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 | Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae  Initial treatment for up to 6 months  Must be treated by 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 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. | Compliance with Authority Required procedures |
| C4306 | P4306 | CN4306 | Rifaximin | Prevention of hepatic encephalopathy  Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist; AND  The treatment must be in combination with lactulose, if lactulose is tolerated; AND  Patient must have had prior episodes of hepatic encephalopathy. | Compliance with Authority Required procedures |
| C4311 | P4311 | CN4311 | Amlodipine with valsartan and hydrochlorothiazide  Olmesartan with amlodipine and hydrochlorothiazide | Hypertension  The treatment must not be for the initiation of anti-hypertensive therapy; AND  The condition must be inadequately controlled with concomitant treatment with two of the following:   an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic. |  |
| C4312 | P4312 | CN4312 | 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  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  Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides);  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 |
| C4313 | P4313 | CN4313 | 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; AND  Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen; AND  Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.  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 4313 |
| 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, 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 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.  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. | Compliance with Authority Required procedures |
| 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 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 | Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae  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. | Compliance with Authority Required 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 |
| C4343 | P4343 | CN4343 | Bimatoprost with timolol  Brimonidine with timolol  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 |
| C4349 | P4349 | CN4349 | Alogliptin | Diabetes mellitus type 2  The treatment must be in combination with metformin; or  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 4349 |
| C4351 | P4351 | CN4351 | Everolimus | Tuberous sclerosis complex (TSC)  Initial 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  Patient must not be a candidate for curative surgical resection. | Compliance with Authority Required procedures |
| 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  The condition must be inadequately controlled with a thiazide diuretic. |  |
| C4363 | P4363 | CN4363 | Pioglitazone | Diabetes mellitus type 2  The treatment must be in combination with metformin; or  The treatment must be in combination with a sulfonylurea; AND  Patient must have a contraindication to a combination of metformin and a sulfonylurea; or  Patient must not have tolerated a combination of metformin and a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 4363 |
| C4364 | P4364 | CN4364 | Pioglitazone | Diabetes mellitus type 2  The treatment must be in combination with metformin; AND  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 4364 |
| C4368 | P4368 | CN4368 | Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids  Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides  Amino acids-synthetic, formula | Eosinophilic oesophagitis  Initial treatment for up to 3 months  Must be treated by a clinical immunologist, suitably qualified allergist or 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. | Compliance with Authority Required procedures |
| C4369 | P4369 | CN4369 | Dabigatran etexilate | Prevention of venous thromboembolism  Patient must be undergoing total hip replacement; AND  Patient must require up to 20 days supply to complete a course of treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 4369 |
| C4373 | P4373 | CN4373 | Amlodipine with valsartan  Olmesartan with amlodipine  Telmisartan with amlodipine | 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 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  Dabigatran etexilate | Prevention of venous thromboembolism  Patient must be undergoing total knee replacement; AND  Patient must require up to 10 days of therapy. | Compliance with Authority Required procedures - 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 |
| C4388 | P4388 | CN4388 | Pioglitazone | Diabetes mellitus type 2  The treatment must be in combination with insulin; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 4388 |
| C4389 | P4389 | CN4389 | Enalapril with hydrochlorothiazide  Fosinopril with hydrochlorothiazide  Quinapril 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 4397 |
| 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 polyunsaturated fatty acids and medium chain triglycerides  Amino acids-synthetic, formula | 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 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. | Compliance with Authority Required procedures |
| 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. |  |
| C4423 | P4423 | CN4423 | Alogliptin with metformin | Diabetes mellitus type 2  Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 4423 |
| C4427 | P4427 | CN4427 | Alogliptin with metformin | Diabetes mellitus type 2  Continuing  Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 4427 |
| C4433 | P4433 | CN4433 | Pamidronic acid | Hypercalcaemia of malignancy  Patient must have a malignancy refractory to anti-neoplastic therapy. | Compliance with Authority Required 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  Ritonavir  Zidovudine | 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 |
| C4456 | P4456 | CN4456 | Tobramycin | Proven Pseudomonas aeruginosa infection  Initial treatment  Patient must have cystic fibrosis; AND  Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result; AND  Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records;  Patient must be 6 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4456 |
| 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 |
| C4473 | P4473 | CN4473 | Afatinib  Erlotinib  Gefitinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment  The treatment must be as monotherapy; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND  Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); or  Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal; AND  Patient must have a WHO performance status of 2 or less;  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 |
| C4475 | P4475 | CN4475 | Doxycycline | Chronic bronchitis  Patient must be aged 8 years or older. |  |
| C4485 | P4485 | CN4485 | Doxycycline | Urethritis |  |
| C4490 | P4490 | CN4490 | Adefovir | 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 4490 |
| C4504 | P4504 | CN4504 | Denosumab | Giant cell tumour of bone  Patient must be one in whom surgical resection is not feasible; or  Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity;  Patient must be an adult. or  Patient must be a skeletally mature adolescent. | Compliance with Authority Required procedures - Streamlined Authority Code 4504 |
| C4510 | P4510 | CN4510 | Adefovir | 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 4510 |
| C4512 | P4512 | CN4512 | Abacavir  Atazanavir  Atazanavir with cobicistat  Dolutegravir  Emtricitabine with tenofovir alafenamide  Lamivudine  Lamivudine with zidovudine  Lopinavir with ritonavir  Nevirapine  Raltegravir  Rilpivirine  Ritonavir  Zidovudine | 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 |
| C4513 | P4513 | CN4513 | Tobramycin | Proven Pseudomonas aeruginosa infection  Continuing treatment  Patient must have cystic fibrosis; AND  Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules; AND  Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s);  Patient must be 6 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 4513 |
| C4514 | P4514 | CN4514 | Doxycycline | Pelvic inflammatory disease |  |
| C4516 | P4516 | CN4516 | Aclidinium  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 |
| C4524 | P4524 | CN4524 | Infliximab | Acute severe ulcerative colitis  Must be treated by a gastroenterologist; or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology]; AND  Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application; AND  Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following:   (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; or  Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below; AND  Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital;  Patient must be 6 years of age or older.  For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where  (i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L  (ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.  For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.  At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.  Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.  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 4524 |
| C4526 | P4526 | CN4526 | Nevirapine | HIV infection  Initial  Patient must have been stabilised on nevirapine immediate release; AND  The treatment must be in combination with other antiretroviral agents. | Compliance with Authority Required procedures - Streamlined Authority Code 4526 |
| 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  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. | Compliance with Authority Required procedures - 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 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. | Compliance with Authority Required 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 |
| C4572 | P4572 | CN4572 | Bimatoprost 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. |  |
| 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. |  |
| 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 unknown type. | Compliance with Authority Required procedures - Streamlined Authority Code 4600 |
| 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 |  |
| C4656 | P4656 | CN4656 | Perampanel | Intractable partial epileptic seizures  Initial  The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents; AND  Must be treated by a neurologist. | Compliance with Authority Required procedures - Streamlined Authority Code 4656 |
| 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 |
| C4658 | P4658 | CN4658 | Perampanel | Intractable partial epileptic seizures  Continuing  Patient must have previously been issued with an authority prescription for this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 4658 |
| 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  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. |  |
| C4683 | P4683 | CN4683 | Voriconazole | Serious invasive mycosis infections  Treatment and maintenance therapy  The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis. | Compliance with Authority Required procedures |
| C4685 | P4685 | CN4685 | Voriconazole | Prophylaxis of invasive fungal infections including both yeasts and moulds  Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome. or  Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant. or  Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment. | Compliance with Authority Required procedures |
| 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 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. |  |
| 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  Escitalopram  Fluoxetine  Fluvoxamine  Paroxetine  Sertraline | Major depressive disorders |  |
| 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  Patient must have a contraindication to cisplatin according to the TGA-approved Product Information. | Compliance with Authority Required procedures - Streamlined Authority Code 4788 |
| 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;  Patient must not be pre-menopausal. | Compliance with Authority Required procedures |
| C4824 | P4824 | CN4824 | Olsalazine | Ulcerative colitis  Patient must have had a documented hypersensitivity reaction to a sulphonamide. or  Patient must be intolerant to sulfasalazine. | Compliance with Authority Required procedures - Streamlined Authority Code 4824 |
| 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 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. | Compliance with Authority Required procedures |
| C4872 | P4872 | CN4872 | Hydrocortisone  Prednisolone | Ulcerative colitis |  |
| C4877 | P4877 | CN4877 | Pamidronic acid  Risedronic acid | Symptomatic Paget disease of bone |  |
| C4878 | P4878 | CN4878 | Mesalazine | Acute episode of mild to moderate ulcerative proctitis |  |
| C4888 | P4888 | CN4888 | Mesalazine | Acute episode of mild to moderate ulcerative colitis | Compliance with Authority Required procedures - Streamlined Authority Code 4888 |
| 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). |  |
| C4893 | P4893 | CN4893 | Hydrocortisone  Prednisolone | Proctitis |  |
| C4894 | P4894 | CN4894 | Paraffin  Sulfasalazine | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| 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  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. | Compliance with 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  Patient must be undergoing percutaneous coronary intervention. | Compliance with Authority Required procedures - Streamlined Authority Code 4919 |
| C4922 | P4922 | CN4922 | Ibandronic acid | Bone metastases  The condition must be due to breast cancer. |  |
| 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 |  |
| C4928 | P4928 | CN4928 | Gabapentin  Tiagabine  Zonisamide | Partial epileptic seizures  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 4928 |
| C4929 | P4929 | CN4929 | Vigabatrin | Epileptic seizures  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 4929 |
| 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 records when PBS-subsidised treatment is initiated | Compliance with Authority Required procedures - Streamlined Authority Code 4937 |
| 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. |  |
| 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 |  |
| C4972 | P4972 | CN4972 | Ganciclovir | Cytomegalovirus disease  Prophylaxis  Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 4972 |
| 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 |
| C4989 | P4989 | CN4989 | Valganciclovir | Cytomegalovirus infection and disease  Prophylaxis  Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 4989 |
| C4991 | P4991 | CN4991 | Dapagliflozin  Empagliflozin | Diabetes mellitus type 2  The treatment must be in combination with insulin; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 4991 |
| C4993 | P4993 | CN4993 | Entecavir  Lamivudine | Chronic hepatitis B infection  Patient must not have cirrhosis; AND  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  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  Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy. | Compliance with Authority Required procedures - Streamlined Authority Code 4993 |
| C4996 | P4996 | CN4996 | Captopril | Patients unable to take a solid dose form of an ACE inhibitor. |  |
| C4997 | P4997 | CN4997 | Progesterone | Assisted Reproductive Technology  The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women; AND  Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.  The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement. | Compliance with Authority Required procedures - Streamlined Authority Code 4997 |
| C4998 | P4998 | CN4998 | Clozapine | Schizophrenia  Continuing treatment  Must be treated by a psychiatrist; or  Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist; AND  Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND  Patient must have completed at least 18 weeks therapy; AND  Patient must be on a clozapine dosage considered stable by a treating psychiatrist; AND  The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.  A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised. | Compliance with Authority Required procedures - Streamlined Authority Code 4998 |
| C4999 | P4999 | CN4999 | Ganciclovir | Cytomegalovirus disease  Prophylaxis  Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 4999 |
| 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 |
| C5004 | P5004 | CN5004 | Peginterferon alfa-2a | Chronic hepatitis C infection  Must be treated in an accredited treatment centre;  Patient must be aged 18 years or older;  Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age;  Patient must have compensated liver disease; AND  Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND  Patient must have a contraindication to ribavirin; AND  The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND  The treatment must be limited to a maximum duration of 48 weeks.  Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5004 |
| 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 phenylalanine | Phenylketonuria |  |
| C5014 | P5014 | CN5014 | Etravirine | HIV infection  The treatment must be in addition to optimised background therapy; AND  The treatment must be in combination with other antiretroviral agents; AND  Patient must be antiretroviral experienced; 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. | Compliance with Authority Required procedures - Streamlined Authority Code 5014 |
| C5015 | P5015 | CN5015 | Clozapine | Schizophrenia  Initial treatment  Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient; AND  Patient must be non-responsive to other neuroleptic agents. or  Patient must be intolerant of other neuroleptic agents.  Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.  The name of the consulting psychiatrist should be included in the patient's medical records.  A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised. | Compliance with Authority Required procedures - Streamlined Authority Code 5015 |
| C5027 | P5027 | CN5027 | Follitropin alfa  Follitropin beta  Follitropin delta  Human menopausal 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 5027 |
| 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  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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 5044 |
| C5045 | P5045 | CN5045 | Progesterone | Assisted Reproductive Technology  The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women; AND  Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.  The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement. | Compliance with Authority Required procedures - Streamlined Authority Code 5045 |
| C5046 | P5046 | CN5046 | Cetrorelix  Ganirelix  Nafarelin  Triptorelin | Assisted Reproductive Technology  The treatment must be for prevention of premature luteinisation and ovulation; AND  Patient must be undergoing controlled ovarian stimulation; AND  Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5046 |
| C5083 | P5083 | CN5083 | Apixaban | Pulmonary embolism  Continuing treatment  Patient must have confirmed acute symptomatic pulmonary embolism. | Compliance with Authority Required procedures - Streamlined Authority Code 5083 |
| C5087 | P5087 | CN5087 | Poly-l-lactic acid | Severe facial lipoatrophy  Initial 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 |
| C5089 | P5089 | CN5089 | Calcitriol  Sodium acid phosphate | Hypophosphataemic rickets | Compliance with Authority Required procedures - Streamlined Authority 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 | 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 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. |  |
| C5131 | P5131 | CN5131 | Pramipexole | Parkinson disease |  |
| C5132 | P5132 | CN5132 | Amantadine | Parkinson disease  The condition must not be drug induced. |  |
| C5133 | P5133 | CN5133 | Entacapone  Opicapone | Parkinson disease  The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination; AND  Patient must be experiencing fluctuations in motor function due to end-of-dose effect. |  |
| 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 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 | Migraine attack  The condition must have usually failed to respond to analgesics in the past. |  |
| C5168 | P5168 | CN5168 | Cabergoline | Parkinson disease |  |
| C5169 | P5169 | CN5169 | Posaconazole | Fungal infection  The condition must be fusariosis; or  The condition must be zygomycosis; or  The condition must be coccidioidomycosis; or  The condition must be chromoblastomycosis; or  The condition must be mycetoma; AND  Patient must be unable to tolerate alternative therapy. or  Patient must have disease refractory to alternative therapy. | Compliance with Authority Required procedures |
| 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. |  |
| C5173 | P5173 | CN5173 | Topiramate | Seizures  Patient must have partial epileptic seizures; or  Patient must have primary generalised tonic-clonic seizures; or  Patient must have seizures of the Lennox-Gastaut syndrome; AND  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; AND  Patient must be unable to take a solid dose form of topiramate. | Compliance with Authority Required procedures - Streamlined Authority Code 5173 |
| 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 |
| C5183 | P5183 | CN5183 | Oxcarbazepine | Seizures  Patient must have partial epileptic seizures; or  Patient must have primary generalised tonic-clonic seizures; AND  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 5183 |
| C5212 | P5212 | CN5212 | Levodopa with carbidopa and entacapone | Parkinson disease  Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone. |  |
| C5214 | P5214 | CN5214 | Levonorgestrel | Contraception |  |
| C5218 | P5218 | CN5218 | Pamidronic acid | Multiple myeloma | Compliance with Authority Required 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 |
| C5224 | P5224 | CN5224 | Isotretinoin | Severe cystic acne  The condition must be unresponsive to other therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5224 |
| 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 |
| C5250 | P5250 | CN5250 | Follitropin alfa with lutropin alfa | Stimulation of follicular development  Patient must have severe LH deficiency; AND  Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment; AND  Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule. | Compliance with Authority Required procedures - Streamlined Authority Code 5250 |
| 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 Code 5251 |
| C5253 | P5253 | CN5253 | Levodopa with carbidopa | Parkinson disease  The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor. |  |
| C5255 | P5255 | CN5255 | Calcitriol | Hypoparathyroidism | Compliance with Authority Required procedures - Streamlined Authority Code 5255 |
| C5259 | P5259 | CN5259 | Sumatriptan | Migraine attack  The condition must have usually failed to respond to analgesics in the past. |  |
| 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 |  |
| C5288 | P5288 | CN5288 | Levodopa with carbidopa and entacapone | Parkinson disease  Patient must be being treated with levodopa decarboxylase inhibitor combinations; AND  Patient must be experiencing fluctuations in motor function due to end-of-dose effect. |  |
| 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.  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 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 permanent withdrawal during treatment with pizotifen.  Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 5325 |
| C5338 | P5338 | CN5338 | Selegiline | Late stage Parkinson disease  The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. |  |
| C5339 | P5339 | CN5339 | Rasagiline | Parkinson disease |  |
| C5340 | P5340 | CN5340 | Tetrabenazine | Hyperkinetic extrapyramidal disorders | Compliance with Authority Required procedures - Streamlined Authority Code 5340 |
| 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 - 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 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. | Compliance with Authority Required procedures - 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 |
| C5363 | P5363 | CN5363 | Pramipexole | Parkinson disease |  |
| 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 |  |
| C5395 | P5395 | CN5395 | Posaconazole | Invasive aspergillosis  Patient must be unable to tolerate alternative therapy. or  Patient must have disease refractory to alternative therapy. | Compliance with Authority Required procedures |
| C5396 | P5396 | CN5396 | Posaconazole | Prophylaxis of invasive fungal infections including both yeasts and moulds  Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome. or  Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.  Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.  Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.  No more than 6 months therapy per episode will be PBS-subsidised | Compliance with Authority Required procedures |
| 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 |
| C5402 | P5402 | CN5402 | Calcitriol | Established osteoporosis  Patient must have fracture due to minimal trauma.  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 5402 |
| C5405 | P5405 | CN5405 | Clostridium botulinum type A toxin - haemagglutinin complex | Blepharospasm or hemifacial spasm  Patient must have blepharospasm; or  Patient must have hemifacial spasm;  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 5405 |
| C5406 | P5406 | CN5406 | Botulinum toxin type A purified neurotoxin complex  Clostridium botulinum type A toxin - haemagglutinin complex | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 5406 |
| C5408 | P5408 | CN5408 | Botulinum toxin type A purified neurotoxin complex | Severe primary axillary hyperhidrosis  Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; or  Patient must be intolerant to topical aluminium chloride hexahydrate 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. | Compliance with Authority Required procedures - Streamlined Authority 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.  The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.  The diagnostic criteria for Restless Legs Syndrome are  (a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and  (b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and  (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  (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. |  |
| C5412 | P5412 | CN5412 | 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 5412 |
| C5413 | P5413 | CN5413 | 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 5413 |
| C5414 | P5414 | CN5414 | Flucloxacillin | Serious staphylococcal infection |  |
| C5415 | P5415 | CN5415 | Dicloxacillin | Serious staphylococcal infection |  |
| C5437 | P5437 | CN5437 | Goserelin | Breast cancer  The condition must be hormone receptor positive. |  |
| C5444 | P5444 | CN5444 | Lansoprazole  Omeprazole  Pantoprazole  Rabeprazole | Gastro-oesophageal reflux disease |  |
| 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 |
| C5451 | P5451 | CN5451 | Tobramycin | Perioperative use in ophthalmic surgery |  |
| 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 |
| C5461 | P5461 | CN5461 | Clobetasol | Moderate to severe scalp psoriasis  The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; or  The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid;  Patient must be aged 18 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 5461 |
| C5464 | P5464 | CN5464 | Anastrozole  Letrozole | Breast cancer  The condition must be hormone receptor positive. |  |
| 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 |
| C5469 | P5469 | CN5469 | Dulaglutide  Semaglutide | Diabetes mellitus type 2  The treatment must be in combination with insulin; AND  The treatment must be in combination with metformin unless contraindicated or not tolerated; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5469 |
| C5470 | P5470 | CN5470 | Clindamycin | Gram-positive coccal infections  The condition must not be able to be safely and effectively treated with a penicillin. |  |
| C5472 | P5472 | CN5472 | Pimecrolimus | Atopic dermatitis  Short-term (up to 3 weeks) intermittent treatment  Patient must be at least 3 months of age;  The condition must be on the patient's face; or  The condition must be on the patient's eyelid; AND  Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy; AND  The condition must have been initially diagnosed more than three months prior to this treatment; AND  Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.  Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by  (i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or  (ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or  (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  (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 | Compliance with Authority Required procedures - Streamlined Authority Code 5472 |
| C5476 | P5476 | CN5476 | Tobramycin | Perioperative use in ophthalmic surgery |  |
| C5477 | P5477 | CN5477 | Tobramycin | Suspected Pseudomonal eye infection |  |
| C5478 | P5478 | CN5478 | Dulaglutide  Semaglutide | Diabetes mellitus type 2  The treatment must be in combination with metformin; AND  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5478 |
| C5482 | P5482 | CN5482 | Pimecrolimus | Atopic dermatitis  Patient must be at least 3 months of age;  The condition must be on the patient's face; or  The condition must be on the patient's eyelid; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 5482 |
| C5483 | P5483 | CN5483 | Tobramycin | Invasive ocular infection |  |
| C5487 | P5487 | CN5487 | Clindamycin | Gram-positive coccal infections  The condition must not be able to be safely and effectively treated with a penicillin. |  |
| C5489 | P5489 | CN5489 | Zolmitriptan | Migraine attack  The condition must have usually failed to respond to analgesics in the past. |  |
| C5490 | P5490 | CN5490 | Tobramycin | Septicaemia, proven |  |
| C5491 | P5491 | CN5491 | Lanthanum  Sevelamer  Sucroferric 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. |  |
| C5499 | P5499 | CN5499 | Tobramycin | Suspected Pseudomonal eye infection |  |
| C5500 | P5500 | CN5500 | Semaglutide | Diabetes mellitus type 2  The treatment must be in combination with metformin; or  The treatment must be in combination with a sulfonylurea; AND  Patient must have a contraindication to a combination of metformin and a sulfonylurea; or  Patient must not have tolerated a combination of metformin and a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5500 |
| 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 |
| 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 |  |
| C5516 | P5516 | CN5516 | Topiramate | Seizures  Patient must have partial epileptic seizures; or  Patient must have primary generalised tonic-clonic seizures; or  Patient must have seizures of the Lennox-Gastaut syndrome; AND  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 5516 |
| C5519 | P5519 | CN5519 | Tobramycin | Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent |  |
| C5520 | P5520 | CN5520 | Tobramycin | Proven Pseudomonas aeruginosa infection  Patient must have cystic fibrosis; AND  The treatment must be for management. | Compliance with Authority Required procedures - Streamlined Authority Code 5520 |
| C5522 | P5522 | CN5522 | Exemestane | 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 |
| C5529 | P5529 | CN5529 | Omeprazole  Pantoprazole | Zollinger-Ellison syndrome |  |
| C5530 | P5530 | CN5530 | 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  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 fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexanoic acid  Amino acid formula with vitamins and minerals without phenylalanine and tyrosine  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 | Tyrosinaemia |  |
| C5534 | P5534 | CN5534 | Amino acid formula with fat, carbohydrate without methionine  Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexanoic acid  Amino acid formula with vitamins and minerals without methionine | 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 |
| C5536 | P5536 | CN5536 | Rifampicin | Meningococcal disease  The treatment must be for prophylaxis; AND  Patient must be a carrier of the disease. or  Patient must be in close contact with people who have the disease. |  |
| 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  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 |  |
| C5550 | P5550 | CN5550 | Flecainide | Serious ventricular cardiac arrhythmias  The treatment must be initiated in a hospital. |  |
| 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 |
| C5552 | P5552 | CN5552 | Rifampicin | Leprosy  Patient must be an adult. | Compliance with Authority Required procedures |
| C5554 | P5554 | CN5554 | Everolimus  Mycophenolic acid | Management of cardiac allograft rejection  Management (initiation, stabilisation and review of therapy)  Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5554 |
| 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 |  |
| C5569 | P5569 | CN5569 | Tacrolimus | Management of rejection in patients following organ or tissue transplantation  The treatment must be under the supervision and direction of a transplant unit; AND  The treatment must include initiation, stabilisation, and review of therapy as required. | Compliance with Authority Required procedures - Streamlined Authority Code 5569 |
| C5571 | P5571 | CN5571 | Amino acid formula with fat, carbohydrate 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 and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid  Amino acid formula without valine, leucine and isoleucine  Isoleucine with carbohydrate  Valine with carbohydrate | Maple syrup urine disease |  |
| C5572 | P5572 | CN5572 | Ponatinib | Acute lymphoblastic leukaemia  Initial treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must be expressing the T315I mutation; AND  Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor; AND  Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).  Failure of treatment is defined as either  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.  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.  The authority application must be made in writing and must include  1. a completed authority prescription form; and  2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and  3. a signed patient acknowledgement; and  4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided | Compliance with Written Authority Required procedures |
| C5584 | P5584 | CN5584 | Flecainide | Serious supra-ventricular cardiac arrhythmias |  |
| C5585 | P5585 | CN5585 | Rifampicin | Haemophilus influenzae type B  The treatment must be for prophylaxis; AND  Patient must be in contact with people who have the disease. |  |
| C5589 | P5589 | CN5589 | Ponatinib | Acute lymphoblastic leukaemia  Continuing treatment  Patient must have previously been issued with an authority prescription for this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have progressive disease. | Compliance with Authority Required procedures |
| C5592 | P5592 | CN5592 | Perhexiline | Angina  The condition must not be responding to other therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5592 |
| C5593 | P5593 | CN5593 | Ciprofloxacin | Chronic suppurative otitis media  Patient must be an Aboriginal or a Torres Strait Islander person;  Patient must be aged 1 month or older. | Compliance with Authority Required procedures |
| C5597 | P5597 | CN5597 | 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 |  |
| C5600 | P5600 | CN5600 | Mycophenolic acid | Management of cardiac allograft rejection  Management (initiation, stabilisation and review of therapy)  Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5600 |
| C5605 | P5605 | CN5605 | Zoledronic acid | Bone metastases  The condition must be due to breast cancer. | Compliance with Authority Required procedures - Streamlined Authority Code 5605 |
| C5607 | P5607 | CN5607 | Albendazole | Hydatid disease  The treatment must be in conjunction with surgery. or  The treatment must be used when a surgical cure cannot be achieved. or  The treatment must be used when surgery cannot be used. | Compliance with Authority Required 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 administration. |  |
| C5624 | P5624 | CN5624 | Voriconazole | Serious fungal infections  Treatment and maintenance therapy  The condition must be caused by Scedosporium species. or  The condition must caused by Fusarium species. | Compliance with Authority Required procedures |
| C5629 | P5629 | CN5629 | Dapagliflozin  Empagliflozin | Diabetes mellitus type 2  The treatment must be in combination with metformin; AND  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 5629 |
| C5630 | P5630 | CN5630 | Brinzolamide with brimonidine | 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. |  |
| C5631 | P5631 | CN5631 | Dapagliflozin with metformin | Diabetes mellitus type 2  Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 5631 |
| C5633 | P5633 | CN5633 | Quinine | Malaria | Compliance with Authority Required procedures - Streamlined Authority Code 5633 |
| C5634 | P5634 | CN5634 | 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 5634 |
| C5635 | P5635 | CN5635 | Dornase alfa | Cystic fibrosis  Continuing treatment  Patient must have initiated treatment with dornase alfa at an age of less than 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. | Compliance with Authority Required procedures - Streamlined Authority 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 |  |
| C5639 | P5639 | CN5639 | Quetiapine | Bipolar I disorder  The treatment must be maintenance therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 5639 |
| 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 |  |
| C5653 | P5653 | CN5653 | Mycophenolic acid | Management of renal allograft rejection  Management (initiation, stabilisation and review of therapy)  Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5653 |
| C5657 | P5657 | CN5657 | Dapagliflozin with metformin  Empagliflozin with metformin | Diabetes mellitus type 2  The treatment must be in combination with insulin; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5657 |
| C5659 | P5659 | CN5659 | Praziquantel | Schistosomiasis | Compliance with Authority Required procedures - Streamlined Authority Code 5659 |
| 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 |
| C5661 | P5661 | CN5661 | Nitrazepam  Temazepam | Malignant neoplasia (late stage) | Compliance with Authority Required procedures |
| C5663 | P5663 | CN5663 | Clarithromycin | Atypical mycobacterial infections |  |
| C5664 | P5664 | CN5664 | Sotalol | Severe cardiac arrhythmias |  |
| C5665 | P5665 | CN5665 | Amiodarone | Severe cardiac arrhythmias |  |
| C5666 | P5666 | CN5666 | Ciprofloxacin | Gonorrhoea | Compliance with Authority Required procedures |
| C5672 | P5672 | CN5672 | Benzydamine | 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 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. | Compliance with Authority Required 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 |
| C5691 | P5691 | CN5691 | Tirofiban | Non-Q-wave myocardial infarction | Compliance with Authority Required procedures - Streamlined Authority Code 5691 |
| C5692 | P5692 | CN5692 | Voriconazole | Serious Candida infections  Treatment and maintenance therapy  The condition must be caused by species not susceptible to fluconazole. or  The condition must be resistant to fluconazole. or  Patient must be unable to tolerate fluconazole. | 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 |
| C5708 | P5708 | CN5708 | Rizatriptan | Migraine attack  The condition must have usually failed to respond to analgesics in the past. |  |
| 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 |
| C5712 | P5712 | CN5712 | Albendazole | Strongyloidiasis | Compliance with Authority Required procedures - Streamlined Authority Code 5712 |
| C5713 | P5713 | CN5713 | Paraffin | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| 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 |
| C5725 | P5725 | CN5725 | Voriconazole | Definite or probable invasive aspergillosis  Treatment and maintenance therapy  Patient must be immunocompromised. | Compliance with Authority Required procedures |
| C5727 | P5727 | CN5727 | Acitretin | Severe disorders of keratinisation | Compliance with Authority Required procedures - Streamlined Authority Code 5727 |
| C5729 | P5729 | CN5729 | Bicalutamide | 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 |
| C5731 | P5731 | CN5731 | Medroxyprogesterone | Advanced breast cancer  The condition must be hormone receptor positive. |  |
| C5732 | P5732 | CN5732 | Benzydamine | Mucositis  The condition must be radiation induced. |  |
| C5734 | P5734 | CN5734 | Voriconazole | Serious invasive mycosis infections  Treatment and maintenance therapy  The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis. | Compliance with Authority Required procedures |
| C5735 | P5735 | CN5735 | Zoledronic acid | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 5735 |
| C5739 | P5739 | CN5739 | Dapagliflozin with metformin | Diabetes mellitus type 2  Continuing treatment  Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin. | Compliance with Authority Required procedures - Streamlined Authority Code 5739 |
| 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 intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | Compliance with Authority Required procedures - Streamlined Authority Code 5740 |
| 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 |
| C5748 | P5748 | CN5748 | Voriconazole | Serious fungal infections  Treatment and maintenance therapy  The condition must be caused by Scedosporium species. or  The condition must caused by Fusarium species. | Compliance with Authority Required procedures |
| 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. |  |
| C5771 | P5771 | CN5771 | Nitrazepam | Myoclonic epilepsy | Compliance with Authority Required procedures |
| 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 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. |  |
| C5779 | P5779 | CN5779 | Pancreatic extract  Pancrelipase | Cystic fibrosis  Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| 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 |
| C5782 | P5782 | CN5782 | Tirofiban | High risk of unstable angina  Patient must have new transient or persistent ST-T ischaemic changes; AND  Patient must have pain lasting longer than 20 minutes. | Compliance with Authority Required procedures - Streamlined Authority Code 5782 |
| C5783 | P5783 | CN5783 | Tenecteplase | Acute myocardial infarction  The treatment must be administrated within 12 hours of onset of attack. |  |
| C5789 | P5789 | CN5789 | Acitretin | Severe intractable psoriasis | Compliance with Authority Required procedures - Streamlined Authority Code 5789 |
| C5791 | P5791 | CN5791 | Medroxyprogesterone | Breast cancer  The condition must be hormone receptor positive. |  |
| C5795 | P5795 | CN5795 | Everolimus  Mycophenolic acid  Sirolimus | Management of renal allograft rejection  Management (initiation, stabilisation and review of therapy)  Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 5795 |
| C5797 | P5797 | CN5797 | Albendazole | Hookworm infestation | Compliance with Authority Required procedures - Streamlined Authority Code 5797 |
| C5798 | P5798 | CN5798 | Dapagliflozin with metformin  Empagliflozin with metformin | Diabetes mellitus type 2  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 5798 |
| 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 |
| C5809 | P5809 | CN5809 | Tirofiban | High risk of unstable angina  Patient must have new transient or persistent ST-T ischaemic changes; AND  Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours. | Compliance with Authority Required procedures - Streamlined Authority Code 5809 |
| C5813 | P5813 | CN5813 | Voriconazole | Definite or probable invasive aspergillosis  Treatment and maintenance therapy  Patient must be immunocompromised. | Compliance with Authority Required procedures |
| C5814 | P5814 | CN5814 | Voriconazole | Serious Candida infections  Treatment and maintenance therapy  The condition must be caused by species not susceptible to fluconazole. or  The condition must be resistant to fluconazole. or  Patient must be unable to tolerate fluconazole. | Compliance with Authority Required procedures |
| C5816 | P5816 | CN5816 | 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 5816 |
| 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;  Patient must identify as Aboriginal or Torres Strait Islander. |  |
| C5820 | P5820 | CN5820 | Folic acid | For treatment of a patient identifying 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 |  |
| C5826 | P5826 | CN5826 | Cefazolin  Cefotaxime  Ceftriaxone | Septicaemia, suspected |  |
| C5830 | P5830 | CN5830 | Ceftriaxone | Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent |  |
| 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 |  |
| C5840 | P5840 | CN5840 | Hydroxocobalamin | Pernicious anaemia  Patient must identify as Aboriginal or Torres Strait Islander. |  |
| C5841 | P5841 | CN5841 | Hydroxocobalamin | Anaemias associated with vitamin B12 deficiency  Patient must have had a gastrectomy; AND  The treatment must be for prophylaxis;  Patient must identify as Aboriginal or Torres Strait Islander. |  |
| C5842 | P5842 | CN5842 | Cefepime | Febrile neutropenia | Compliance with Authority Required procedures |
| 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  Glucose indicator-urine | For treatment of a patient identifying as Aboriginal or Torres Strait Islander |  |
| C5854 | P5854 | CN5854 | Hydroxocobalamin | Proven vitamin B12 deficiencies other than pernicious anaemia  Patient must identify as Aboriginal or Torres Strait Islander. |  |
| C5855 | P5855 | CN5855 | Ceftriaxone | Gonorrhoea |  |
| C5856 | P5856 | CN5856 | Olanzapine | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 5856 |
| 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 |
| C5861 | P5861 | CN5861 | Cefazolin | Septicaemia, suspected |  |
| C5862 | P5862 | CN5862 | Ceftriaxone | Septicaemia, proven |  |
| 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 |  |
| C5868 | P5868 | CN5868 | Ceftriaxone | Septicaemia, suspected |  |
| C5869 | P5869 | CN5869 | Olanzapine | 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;  Patient must identify as Aboriginal or Torres Strait Islander. |  |
| C5881 | P5881 | CN5881 | Cefazolin  Cefotaxime  Ceftriaxone | Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent |  |
| C5882 | P5882 | CN5882 | Cefazolin | Septicaemia, proven |  |
| 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 |  |
| C5890 | P5890 | CN5890 | Cefazolin  Cefotaxime  Ceftriaxone | Septicaemia, proven |  |
| C5891 | P5891 | CN5891 | Cefazolin | Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent |  |
| 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 |
| C5903 | P5903 | CN5903 | Risperidone | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 5903 |
| C5904 | P5904 | CN5904 | 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 |
| C5905 | P5905 | CN5905 | Cefotaxime | Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent |  |
| 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 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 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 |
| C5915 | P5915 | CN5915 | 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 |
| 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 but need not delay treatment. | Compliance with Authority Required procedures - Streamlined Authority 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 triglycerides  Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides | Eosinophilic oesophagitis  Initial treatment for up to 3 months  Must be treated by a clinical immunologist, suitably qualified allergist or 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. | Compliance with Authority Required procedures |
| 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 |
| 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 |
| C5953 | P5953 | CN5953 | Empagliflozin with metformin | Diabetes mellitus type 2  Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 5953 |
| 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 |
| C5957 | P5957 | CN5957 | Ribavirin | Chronic hepatitis C infection  Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND  Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND  The treatment must be limited to a maximum duration of 12 weeks;  Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. | Compliance with Authority Required procedures |
| C5959 | P5959 | CN5959 | Aciclovir | Herpes zoster ophthalmicus | Compliance with Authority Required procedures - Streamlined Authority Code 5959 |
| 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 |  |
| C5966 | P5966 | CN5966 | Empagliflozin with metformin | Diabetes mellitus type 2  Continuing treatment  Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin. | Compliance with Authority Required procedures - Streamlined Authority Code 5966 |
| 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  Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C; AND  Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status; AND  The treatment must be limited to a maximum duration of 12 weeks. | Compliance with Authority Required procedures |
| C5970 | P5970 | CN5970 | Amino acid formula with fat, carbohydrate without phenylalanine  Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine  Protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid | Phenylketonuria |  |
| C5971 | P5971 | CN5971 | Famciclovir | 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 5971 |
| C5973 | P5973 | CN5973 | Folinic acid | Megaloblastic anaemias  The condition must be a result of folic acid deficiency from the use of folic acid antagonists. |  |
| C5974 | P5974 | CN5974 | 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 and medium chain triglycerides | 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 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. | Compliance with Authority Required 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 |
| C5978 | P5978 | CN5978 | Fluconazole | Cryptococcal meningitis  The treatment must be maintenance therapy; AND  Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 5978 |
| 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 |  |
| C5988 | P5988 | CN5988 | Itraconazole | Disseminated pulmonary histoplasmosis infection  Treatment and maintenance therapy  Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS). | Compliance with Authority Required procedures - Streamlined Authority Code 5988 |
| C5989 | P5989 | CN5989 | Fluconazole | Oesophageal candidiasis  Patient must be immunosuppressed. | Compliance with Authority Required procedures - 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 |  |
| C6002 | P6002 | CN6002 | Fluconazole | Cryptococcal meningitis | Compliance with Authority Required procedures - Streamlined Authority Code 6002 |
| C6005 | P6005 | CN6005 | Itraconazole | Systemic sporotrichosis | Compliance with Authority Required procedures - Streamlined Authority Code 6005 |
| C6006 | P6006 | CN6006 | Fluconazole | Cryptococcal meningitis  Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 6006 |
| 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 |
| C6016 | P6016 | CN6016 | Itraconazole | Oropharyngeal candidiasis  Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 6016 |
| 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 |
| C6022 | P6022 | CN6022 | Itraconazole | Systemic aspergillosis | Compliance with Authority Required procedures - Streamlined Authority Code 6022 |
| C6023 | P6023 | CN6023 | Fluconazole | Oropharyngeal candidiasis  Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 6023 |
| 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  Patient must be immunosuppressed. | Compliance with Authority Required procedures - 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 |
| C6035 | P6035 | CN6035 | Itraconazole | Oesophageal candidiasis  Patient must be immunosuppressed. | Compliance with Authority Required procedures - Streamlined Authority Code 6035 |
| C6036 | P6036 | CN6036 | Artemether with lumefantrine | Confirmed or suspected Plasmodium falciparum malaria  Patient must be unable to swallow a solid dosage form of artemether with lumefantrine. |  |
| C6037 | P6037 | CN6037 | Itraconazole | Chronic pulmonary histoplasmosis infection  Treatment and maintenance therapy  Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS). | Compliance with Authority Required procedures - Streamlined Authority Code 6037 |
| C6038 | P6038 | CN6038 | Amino acid formula with vitamins and minerals without methionine | Pyridoxine non-responsive homocystinuria |  |
| C6045 | P6045 | CN6045 | Fluconazole | Cryptococcal meningitis  The treatment must be maintenance therapy; 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 6045 |
| 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. |  |
| C6057 | P6057 | CN6057 | Itraconazole | Systemic histoplasmosis | Compliance with Authority Required procedures - Streamlined Authority Code 6057 |
| C6073 | P6073 | CN6073 | Carmellose  Hypromellose  Hypromellose with carbomer 980  Hypromellose with dextran  Polyethylene glycol 400 with propylene glycol | Severe dry eye syndrome, including Sjogren's syndrome |  |
| C6079 | P6079 | CN6079 | Carmellose with glycerin | Severe dry eye syndrome, including Sjogren's syndrome  Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| 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 - Streamlined Authority Code 6084 |
| C6087 | P6087 | CN6087 | Prednisolone with phenylephrine | Uveitis |  |
| C6097 | P6097 | CN6097 | Carmellose with glycerin | Severe dry eye syndrome, including Sjogren's syndrome |  |
| C6098 | P6098 | CN6098 | Carmellose  Hypromellose  Hypromellose with carbomer 980  Hypromellose with dextran  Polyethylene glycol 400 with propylene glycol | Severe dry eye syndrome, including Sjogren's syndrome  Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| 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 |
| C6120 | P6120 | CN6120 | Carmellose  Hypromellose  Hypromellose with carbomer 980  Hypromellose with dextran  Polyethylene glycol 400 with propylene glycol | Severe dry eye syndrome, including Sjogren's syndrome |  |
| 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  Patient must require a ketogenic diet. | Compliance with 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 |  |
| C6145 | P6145 | CN6145 | Phenoxybenzamine | Phaeochromocytoma |  |
| C6146 | P6146 | CN6146 | Triglycerides, medium chain | Long chain fatty acid oxidation disorders | Compliance with Authority Required procedures - Streamlined Authority Code 6146 |
| 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. |  |
| C6153 | P6153 | CN6153 | Carbomer | Severe dry eye syndrome, including Sjogren's syndrome |  |
| 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 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 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 |
| C6169 | P6169 | CN6169 | Flucloxacillin | Osteomyelitis | Compliance with Authority Required procedures - Streamlined Authority Code 6169 |
| 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  Carbomer 974  Carmellose  Hypromellose  Hypromellose with dextran  Paraffin  Perfluorohexyloctane  Polyethylene glycol 400 with propylene glycol  Soy lecithin | Severe dry eye syndrome  Patient must be sensitive to preservatives in multi-dose eye drops. | Compliance with Authority Required procedures - Streamlined Authority Code 6172 |
| C6174 | P6174 | CN6174 | Protein hydrolysate formula with medium chain triglycerides | Cows' milk protein enteropathy and intolerance to soy protein  Initial treatment  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  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 up to the age of 24 months. | Compliance with Authority Required procedures - Streamlined Authority Code 6174 |
| C6175 | P6175 | CN6175 | Nitrazepam  Temazepam | Insomnia  Patient must be receiving palliative care. | Compliance with Authority Required procedures |
| C6176 | P6176 | CN6176 | Diazepam  Oxazepam | Anxiety  Patient must be receiving palliative care. | Compliance with Authority Required procedures |
| C6178 | P6178 | CN6178 | Phenoxybenzamine | Neurogenic urinary retention |  |
| C6180 | P6180 | CN6180 | Methylnaltrexone | Opioid-induced constipation  The treatment must be in combination with oral laxatives; AND  Patient must be receiving palliative care; AND  Patient must have failed to respond to laxatives. | 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 |
| 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 |
| C6185 | P6185 | CN6185 | Carbomer | Severe dry eye syndrome, including Sjogren's syndrome  Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| C6188 | P6188 | CN6188 | Cefalexin  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 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. | Compliance with Authority Required procedures - 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 - 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 |
| C6206 | P6206 | CN6206 | Protein hydrolysate formula with medium chain triglycerides | Chylothorax | Compliance with Authority Required procedures - Streamlined Authority Code 6206 |
| C6207 | P6207 | CN6207 | Hyoscine | For use in patients receiving palliative care | Compliance with Authority Required procedures - 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  Ketoprofen  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  Methylprednisolone  Mometasone | Corticosteroid-responsive dermatoses  The condition must cover 40-60% of the patient's body surface area. | Compliance with Authority Required 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. |  |
| C6226 | P6226 | CN6226 | Dexamfetamine  Methylphenidate | Attention deficit hyperactivity disorder  Treatment must be in accordance with the law of the relevant State or Territory. | Compliance with Authority Required procedures |
| C6227 | P6227 | CN6227 | Dexamfetamine | Narcolepsy | Compliance with Authority Required procedures |
| 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  Methylprednisolone  Mometasone | Corticosteroid-responsive dermatoses  The condition must cover 10-20% of the patient's body surface area. | Compliance with Authority Required 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 |  |
| 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 |  |
| 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 lipoidica |  |
| 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; AND  The condition must include extensive visceral involvement. | Compliance with Authority Required procedures - Streamlined Authority 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 |  |
| 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 |
| C6295 | P6295 | CN6295 | Clonazepam  Phenobarbital | Epilepsy |  |
| C6296 | P6296 | CN6296 | Clonazepam | Epilepsy  The condition must be neurologically proven. | Compliance with Authority Required procedures |
| 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.  The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 6306 |
| C6307 | P6307 | CN6307 | 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.  The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 6307 |
| C6308 | P6308 | CN6308 | Zoledronic 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; AND  Patient must not receive more than one PBS-subsidised treatment per year.  The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 6308 |
| C6310 | P6310 | CN6310 | Alendronic acid  Risedronic acid | 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. |  |
| C6313 | P6313 | CN6313 | Zoledronic acid | Osteoporosis  Patient must be aged 70 years or older;  Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less; AND  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND  Patient must not receive more than one PBS-subsidised treatment per year.  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 6313 |
| C6314 | P6314 | CN6314 | Raloxifene | Established post-menopausal osteoporosis  Patient must have fracture due to minimal trauma; AND  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 6314 |
| C6315 | P6315 | CN6315 | Alendronic acid with colecalciferol | Established osteoporosis  Patient must have fracture due to minimal trauma; AND  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 6315 |
| C6318 | P6318 | CN6318 | Zoledronic acid | Established osteoporosis  Patient must have fracture due to minimal trauma; AND  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND  Patient must not receive more than one PBS-subsidised treatment per year.  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 6318 |
| C6319 | P6319 | CN6319 | Alendronic acid with colecalciferol | Established osteoporosis  Patient must have fracture due to minimal trauma; AND  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 6319 |
| 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;  Patient must be aged 40 years or older;  Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.  Androgen deficiency is defined as  (i) testosterone level of less than 6 nmol per litre; OR  (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).  Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.  The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.  The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
| C6325 | P6325 | CN6325 | 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 6325 |
| C6327 | P6327 | CN6327 | Alendronic acid  Risedronic acid | Established osteoporosis  Patient must have fracture due to minimal trauma; AND  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that 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 |
| C6333 | P6333 | CN6333 | Linagliptin with metformin  Saxagliptin with metformin  Sitagliptin with metformin  Vildagliptin with metformin | Diabetes mellitus type 2  Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6333 |
| C6334 | P6334 | CN6334 | Sitagliptin with metformin | Diabetes mellitus type 2  Continuing  Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 6334 |
| C6335 | P6335 | CN6335 | Saxagliptin with metformin | Diabetes mellitus type 2  Continuing  Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 6335 |
| C6336 | P6336 | CN6336 | Linagliptin with metformin | Diabetes mellitus type 2  Continuing  Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 6336 |
| 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 procedures |
| C6344 | P6344 | CN6344 | Linagliptin with metformin  Saxagliptin with metformin  Sitagliptin with metformin  Vildagliptin with metformin | Diabetes mellitus type 2  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 6344 |
| C6345 | P6345 | CN6345 | Silver sulfadiazine | Stasis ulcers |  |
| C6346 | P6346 | CN6346 | Linagliptin  Saxagliptin  Sitagliptin  Vildagliptin | Diabetes mellitus type 2  The treatment must be in combination with metformin; or  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 6346 |
| 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 |
| C6357 | P6357 | CN6357 | Vildagliptin with metformin | Diabetes mellitus type 2  Continuing  Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 6357 |
| C6359 | P6359 | CN6359 | Dantrolene | Chronic spasticity |  |
| C6362 | P6362 | CN6362 | Silver sulfadiazine | Infection  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. |  |
| C6363 | P6363 | CN6363 | Linagliptin  Saxagliptin  Sitagliptin  Vildagliptin | Diabetes mellitus type 2  The treatment must be in combination with metformin; AND  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 6363 |
| 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 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 be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.  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 6370 |
| C6376 | P6376 | CN6376 | Linagliptin  Sitagliptin  Vildagliptin | Diabetes mellitus type 2  The treatment must be in combination with insulin; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 6376 |
| C6377 | P6377 | CN6377 | Darunavir with cobicistat | 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 not be in combination with ritonavir; 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 6377 |
| C6381 | P6381 | CN6381 | Tamoxifen | Breast cancer  The condition must be hormone receptor positive. |  |
| C6382 | P6382 | CN6382 | Liothyronine | Thyroid cancer | Compliance with Authority Required procedures - Streamlined Authority Code 6382 |
| C6383 | P6383 | CN6383 | Aprepitant | Nausea and vomiting  The condition must be associated with 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 be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.  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 6383 |
| 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 |
| 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 |  |
| C6410 | P6410 | CN6410 | Liothyronine | Hypothyroidism  The treatment must be for replacement therapy; AND  Patient must have documented intolerance to levothyroxine sodium. or  Patient must have documented resistance to levothyroxine sodium. | Compliance with Authority Required procedures - Streamlined Authority Code 6410 |
| 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 |
| C6421 | P6421 | CN6421 | Tamoxifen | Reduction of breast cancer risk  Patient must have a moderate or high risk of developing breast cancer; AND  The treatment must not exceed a dose of 20 mg per day; AND  The treatment must not exceed a lifetime maximum of 5 years for this condition. |  |
| 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 |
| C6429 | P6429 | CN6429 | Colestyramine | Primary hypercholesterolaemia  Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| C6434 | P6434 | CN6434 | Ketoconazole  Miconazole  Terbinafine | Fungal or yeast infection  Patient must be an Aboriginal or a Torres Strait Islander person. | Compliance with Authority Required procedures - Streamlined Authority Code 6434 |
| C6443 | P6443 | CN6443 | Linagliptin with metformin  Sitagliptin with metformin  Vildagliptin with metformin | Diabetes mellitus type 2  The treatment must be in combination with insulin; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 6443 |
| C6444 | P6444 | CN6444 | 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 6444 |
| C6448 | P6448 | CN6448 | 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 6448 |
| C6449 | P6449 | CN6449 | Tamoxifen | Breast cancer  The condition must be hormone receptor positive. |  |
| C6453 | P6453 | CN6453 | Terbinafine | Dermatophyte infection  Patient must have failed to respond to topical treatment; AND  Patient must have failed to respond to griseofulvin;  Patient must be 18 years of age or less. | Compliance with Authority Required procedures |
| 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  The condition must be visually proven; AND  The treatment must not be within 2 years of the end of the previous course of treatment with this drug; AND  Patient must have had a recent bone density assessment.  The date of the bone density assessment must be recorded in the patient's medical records. |  |
| C6524 | P6524 | CN6524 | Denosumab | Established osteoporosis  Patient must have fracture due to minimal trauma; AND  Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 6524 |
| C6548 | P6548 | CN6548 | Denosumab | 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 6548 |
| C6552 | P6552 | CN6552 | Nafarelin | Endometriosis  Initial treatment, for up to 6 months  The condition must be visually proven. |  |
| C6562 | P6562 | CN6562 | Ipilimumab | Unresectable Stage III or Stage IV malignant melanoma  Induction treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not have received prior treatment with ipilimumab; AND  The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 6562 |
| C6578 | P6578 | CN6578 | Lenvatinib | Locally advanced or metastatic differentiated thyroid cancer  Continuing treatment  The condition must be refractory to radioactive iodine; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST). | Compliance with Authority Required procedures - Streamlined Authority Code 6578 |
| C6585 | P6585 | CN6585 | Ipilimumab | Unresectable Stage III or Stage IV malignant melanoma  Re-induction treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction); AND  The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.  An initial objective response to treatment is defined as either  (i) sustained stable disease of greater than or equal to 3 months duration measured from at least 2 weeks after the date of completion of the most recent course of ipilimumab; or  (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. | Compliance with Authority Required procedures - Streamlined Authority Code 6585 |
| C6604 | P6604 | CN6604 | Lenvatinib | Locally advanced or metastatic differentiated thyroid cancer  Initial treatment  The condition must be refractory to radioactive iodine; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have symptomatic progressive disease prior to treatment; or  Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures; AND  Patient must have thyroid stimulating hormone adequately repressed; AND  Patient must be one in whom surgery is inappropriate; AND  Patient must not be a candidate for radiotherapy with curative intent; AND  Patient must have a WHO performance status of 2 or less.  Radioactive iodine refractory is defined as:  a lesion without iodine uptake on a radioactive iodine (RAI) scan; or  having received a cumulative RAI dose of greater than or equal to 600 mCi; or  progression within 12 months of a single RAI treatment; or  progression after two RAI treatments administered within 12 months of each other. | Compliance with Authority Required procedures - Streamlined Authority Code 6604 |
| 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  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. | Compliance with 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 |
| C6645 | P6645 | CN6645 | Riociguat | Chronic thromboembolic pulmonary hypertension (CTEPH)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must demonstrate stable or responding disease; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Must be treated in a centre with expertise in the management of CTEPH;  Patient must be aged 18 years or older.  Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed CTEPH PBS Continuing Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT).  Test requirements to establish response to treatment for continuation of treatment are as follows  The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment  (1) RHC plus ECHO composite assessments plus 6MWT;  (2) RHC plus ECHO composite assessments;  (3) RHC composite assessment plus 6MWT;  (4) ECHO composite assessment plus 6MWT;  (5) RHC composite assessment only;  (6) ECHO composite assessment only.  The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.  The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.  Response to this drug is defined as follows  For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.  For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.  For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.  The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.  The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.  A maximum of 5 repeats will be authorised.  Applications for continuing treatment with this drug should be made two weeks prior to the completion of the 6-month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.  Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. | Compliance with Written Authority Required procedures |
| 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 |
| 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 |
| C6664 | P6664 | CN6664 | Riociguat | Chronic thromboembolic pulmonary hypertension (CTEPH)  Initial treatment  Patient must have WHO Functional Class II, III or IV CTEPH; AND  The condition must be inoperable by pulmonary endarterectomy; or  The condition must be recurrent or persistent following pulmonary endarterectomy; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Must be treated in a centre with expertise in the management of CTEPH;  Patient must be aged 18 years or older.  CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:  Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn\*sec\*cm-5 measured at least 90 days after start of full anticoagulation; and  A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.  CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:  RHC demonstrating a PVR of greater than 300 dyn\*sec\*cm-5 measured at least 180 days following pulmonary endarterectomy.  Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be provided at the time of application.  Applications for authorisation must be in writing and must include: (1) completed authority prescription forms sufficient for dose titration; and (2) a completed CTEPH PBS Initial Authority Application - Supporting Information form which includes results from the 3 tests below, to establish baseline measurements, where available: (i) RHC composite assessment, and (ii) ECHO composite assessment, and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgment form; and (4) confirmation of evidence of inoperable CTEPH including results of a pulmonary vascular resistance (PVR), a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or (5) confirmation of evidence of recurrent or persistent CTEPH including result of PVR and the date that pulmonary endarterectomy was performed; or (6) confirmation of an echocardiogram demonstrating right ventricular dysfunction.  Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: Where it is not possible to perform all 3 tests above on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only.  In circumstance where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only.  Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.  The test results provided must not be more than 2 months old at the time of application.  Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.  Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.  The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.  Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. | Compliance with Written Authority Required procedures |
| 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  The treatment must be an alternative to sodium cromoglycate. or  The treatment must be an alternative to nedocromil sodium. | Compliance with Authority Required procedures - Streamlined Authority Code 6666 |
| 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  Ustekinumab | Severe chronic plaque psoriasis  Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply  Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C6706 | P6706 | CN6706 | Bromocriptine | Pathological hyperprolactinaemia  Patient must have had surgery for this condition with incomplete resolution. |  |
| C6707 | P6707 | CN6707 | Bromocriptine | Pathological hyperprolactinaemia  Patient must be one in whom radiotherapy is not indicated. |  |
| C6717 | P6717 | CN6717 | Bromocriptine | Acromegaly |  |
| C6718 | P6718 | CN6718 | Bromocriptine | Parkinson disease |  |
| C6719 | P6719 | CN6719 | Bromocriptine | Pathological hyperprolactinaemia  Patient must have had radiotherapy for this condition with incomplete resolution. |  |
| C6732 | P6732 | CN6732 | Ceritinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment  The treatment must be as monotherapy; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND  Patient must have a WHO performance status of 2 or less;  Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing. | Compliance with Authority Required procedures |
| C6752 | P6752 | CN6752 | Trametinib | 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 dabrafenib concomitantly for this condition; AND  Patient must have stable or responding disease. | Compliance with Authority Required procedures - Streamlined Authority Code 6752 |
| C6773 | P6773 | CN6773 | Alprazolam | 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. | Compliance with Authority Required procedures |
| 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  Patient must not show continuing progression of disability while on treatment with this drug; AND  Patient must not receive more than one PBS-subsidised treatment per year; 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 6847 |
| C6852 | P6852 | CN6852 | Fosaprepitant | Nausea and vomiting  The condition must be associated with 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 be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 6852 |
| C6860 | P6860 | CN6860 | Glatiramer  Interferon beta-1b  Peginterferon beta-1a | Multiple sclerosis  Continuing treatment  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not show continuing progression of disability while on treatment with this drug; AND  Patient must have demonstrated compliance with, and an ability to tolerate this therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6860 |
| C6871 | P6871 | CN6871 | Varenicline | Nicotine dependence  Commencement 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 indicated they are ready to cease smoking; AND  Patient must not receive more than 24 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 6871 |
| 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 patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 6882 |
| C6885 | P6885 | CN6885 | Varenicline | Nicotine dependence  Completion of a short-term (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 PBS-subsidised treatment with this drug during this current course of treatment; AND  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  Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program. | Compliance with Authority Required procedures - Streamlined Authority Code 6885 |
| C6886 | P6886 | CN6886 | Fosaprepitant | Nausea and vomiting  The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND  The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone; AND  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.  No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. | Compliance with Authority Required procedures - Streamlined Authority Code 6886 |
| C6887 | P6887 | CN6887 | Fosaprepitant | 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 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. | Compliance with Authority Required procedures - Streamlined Authority 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 |
| C6897 | P6897 | CN6897 | 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 6897 |
| 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 |
| C6899 | P6899 | CN6899 | Risperidone | Severe behavioural disturbances  Continuing treatment  Patient must have autism spectrum disorder; AND  Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age; 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 aged 18 years or older.  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 6899 |
| 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 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 |
| 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 |
| C6938 | P6938 | CN6938 | Risperidone | Severe behavioural disturbances  Continuing treatment  Patient must have autism spectrum disorder; AND  Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age; 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 aged 18 years or older.  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 6938 |
| 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 antispastic agents; AND  Patient must have chronic spasticity due to multiple sclerosis. | Compliance with Authority Required procedures - Streamlined Authority 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 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 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. | Compliance with Authority Required procedures - Streamlined Authority Code 6984 |
| 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  Patient must be nucleoside analogue naive; AND  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  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  Patient must have evidence of chronic liver injury determined by:   (i) confirmed elevated serum ALT; or (ii) liver biopsy; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 6992 |
| C6995 | P6995 | CN6995 | Chorionic gonadotrophin | Hypogonadism or delayed puberty  Patient must be male;  Patient must be aged 16 years or older;  Patient must show clinical evidence of the condition; AND  The treatment must not extend beyond 6 months. |  |
| C6998 | P6998 | CN6998 | Tenofovir | 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 6998 |
| C7025 | P7025 | CN7025 | 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  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 surgery and where radiotherapy is contraindicated; AND  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  The treatment must cease if IGF1 is not lower after 3 months of treatment; AND  The treatment must not be given concomitantly with PBS-subsidised pegvisomant.  In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | Compliance with Authority Required procedures - Streamlined Authority Code 7025 |
| C7046 | P7046 | CN7046 | Omalizumab | Severe chronic spontaneous urticaria  Continuing treatment  Must be treated by a clinical immunologist; or  Must be treated by an allergist; or  Must be treated by a dermatologist; or  Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU); AND  Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition; AND  Patient must not receive more than 24 weeks per authorised course of treatment under this restriction. | Compliance with Authority Required procedures |
| C7055 | P7055 | CN7055 | Omalizumab | Severe chronic spontaneous urticaria  Initial treatment  Must be treated by a clinical immunologist; or  Must be treated by an allergist; or  Must be treated by a dermatologist; or  Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU); AND  The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria); AND  Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines; AND  Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy; AND  Patient must not receive more than 12 weeks of treatment under this restriction.  A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following  1) a H2 receptor antagonist (150 mg twice per day); or  2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or  3) doxepin (up to 25 mg three times a day)  If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.  A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.  The authority application must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include  (i) demonstration of failure to achieve an adequate response to standard therapy; and  (ii) drug names and doses of standard therapies that the patient has failed; and  (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient. | Compliance with Written Authority Required procedures |
| C7087 | P7087 | CN7087 | Pegvisomant | Acromegaly  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue; AND  The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.  Somatostatin analogues include octreotide, lanreotide and pasireotide  In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.  Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).  In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application. | Compliance with Authority Required procedures |
| C7134 | P7134 | CN7134 | 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 7134 |
| C7148 | P7148 | CN7148 | 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 7148 |
| C7152 | P7152 | CN7152 | 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 7152 |
| C7153 | P7153 | CN7153 | 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 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 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. | Compliance with Authority Required procedures |
| 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 |
| C7289 | P7289 | CN7289 | Etanercept | Severe chronic plaque psoriasis  Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply  Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND  The treatment must be as systemic monotherapy (other than methotrexate);  Patient must be aged 18 years or older;  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C7345 | P7345 | CN7345 | Alectinib | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  Initial treatment  The treatment must be as monotherapy; AND  The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND  Patient must have a WHO performance status of 2 or less;  Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing. | Compliance with Authority Required procedures |
| C7346 | P7346 | CN7346 | Alectinib  Brigatinib | 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 develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C7362 | P7362 | CN7362 | 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.  Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | Compliance with Authority Required procedures - Streamlined Authority Code 7362 |
| C7367 | P7367 | CN7367 | Mannitol | Cystic fibrosis  The treatment must be in combination with dornase alfa; AND  Patient must be inadequately responsive to dornase alfa; AND  Patient must have trialled hypertonic saline for this condition;  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.  Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | Compliance with Authority Required procedures - Streamlined Authority Code 7367 |
| C7369 | P7369 | CN7369 | 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 drug for this condition; AND  Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C7374 | P7374 | CN7374 | Deferasirox | Chronic iron overload  Initial treatment  Patient must not be transfusion dependent; AND  The condition must be thalassaemia. | Compliance with Authority Required procedures |
| 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  Patient must have received an initial authority prescription for this drug for this condition; AND  Patient must have demonstrated a response to prior treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 7431 |
| C7432 | P7432 | CN7432 | Everolimus | 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 7432 |
| C7433 | P7433 | CN7433 | Axitinib | 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 7433 |
| C7446 | P7446 | CN7446 | 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 received an initial authority prescription for this drug for this condition; AND  Patient must not have progressive disease;  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 7446 |
| 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 7471 |
| 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 | Hypsarrhythmia 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  Vismodegib | Metastatic or locally advanced basal cell carcinoma (BCC)  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. | Compliance with Authority Required procedures |
| C7492 | P7492 | CN7492 | Dapagliflozin with metformin  Empagliflozin with metformin | Diabetes mellitus type 2  Continuing treatment  The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND  Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7492 |
| C7495 | P7495 | CN7495 | Dapagliflozin  Empagliflozin | Diabetes mellitus type 2  Continuing treatment  The treatment must be in combination with metformin; AND  The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND  Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7495 |
| C7498 | P7498 | CN7498 | Dapagliflozin with metformin  Empagliflozin with metformin | Diabetes mellitus type 2  Initial treatment  The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND  Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition. or  Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.  The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7498 |
| C7505 | P7505 | CN7505 | Linagliptin  Saxagliptin  Sitagliptin | Diabetes mellitus type 2  Continuing treatment  The treatment must be in combination with metformin; AND  The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND  Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7505 |
| C7506 | P7506 | CN7506 | Dapagliflozin  Empagliflozin | Diabetes mellitus type 2  The treatment must be in combination with metformin; or  The treatment must be in combination with a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records.  A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 7506 |
| C7507 | P7507 | CN7507 | Linagliptin with metformin  Saxagliptin with metformin  Sitagliptin with metformin | Diabetes mellitus type 2  Initial treatment  The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND  Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition. or  Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.  The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7507 |
| C7509 | P7509 | CN7509 | Lanreotide | Functional carcinoid tumour  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  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 7509 |
| 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 |
| C7524 | P7524 | CN7524 | Empagliflozin with linagliptin  Saxagliptin with dapagliflozin | Diabetes mellitus type 2  Initial treatment  The treatment must be in combination with metformin; AND  Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor. or  Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.  The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7524 |
| 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 |
| C7528 | P7528 | CN7528 | Dapagliflozin  Empagliflozin | Diabetes mellitus type 2  Initial treatment  The treatment must be in combination with metformin; AND  The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND  Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin. or  Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.  The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7528 |
| C7530 | P7530 | CN7530 | Linagliptin with metformin  Saxagliptin with metformin  Sitagliptin with metformin | Diabetes mellitus type 2  Continuing treatment  The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND  Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7530 |
| C7532 | P7532 | CN7532 | Lanreotide | Acromegaly  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  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 surgery and where radiotherapy is contraindicated; AND  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  The treatment must cease if IGF1 is not lower after 3 months of treatment; AND  The treatment must not be given concomitantly with PBS-subsidised pegvisomant.  In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | Compliance with Authority Required procedures - Streamlined Authority Code 7532 |
| C7541 | P7541 | CN7541 | Linagliptin  Saxagliptin  Sitagliptin | Diabetes mellitus type 2  Initial treatment  The treatment must be in combination with metformin; AND  The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND  Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor. or  Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.  The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7541 |
| C7556 | P7556 | CN7556 | Empagliflozin with linagliptin  Saxagliptin with dapagliflozin | Diabetes mellitus type 2  Continuing treatment  The treatment must be in combination with metformin; AND  Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 7556 |
| 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 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. | Compliance with Authority Required procedures |
| 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 |
| C7598 | P7598 | CN7598 | Atorvastatin  Fluvastatin  Pravastatin  Rosuvastatin  Simvastatin | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| 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  The treatment must be limited to a maximum duration of 12 weeks. | Compliance with Authority Required procedures |
| C7621 | P7621 | CN7621 | Balsalazide | Ulcerative colitis  Patient must have had a documented hypersensitivity reaction to a sulphonamide. or  Patient must be intolerant to sulfasalazine. | Compliance with Authority Required procedures - Streamlined Authority Code 7621 |
| C7629 | P7629 | CN7629 | Riociguat | Chronic thromboembolic pulmonary hypertension (CTEPH)  Balance of supply  Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; or  Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction; AND  The treatment must be the sole PBS-subsidised agent for this condition; AND  Must be treated in a centre with expertise in the management of CTEPH;  Patient must be aged 18 years or older. | Compliance with Authority Required procedures |
| C7631 | P7631 | CN7631 | Cabozantinib | Stage IV clear cell variant renal cell carcinoma (RCC)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 7631 |
| C7640 | P7640 | CN7640 | Fenofibrate  Gemfibrozil | For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements. |  |
| C7645 | P7645 | CN7645 | Dulaglutide | Diabetes mellitus type 2  The treatment must be in combination with metformin; AND  Patient must have a contraindication to a combination of metformin and a sulfonylurea; or  Patient must not have tolerated a combination of metformin and a sulfonylurea; AND  Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin. or  Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.  The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.  The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.  Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances  (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or  (b) Had red cell transfusion within the previous 3 months.  The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7645 |
| C7695 | P7695 | CN7695 | Glatiramer  Interferon beta-1b  Peginterferon beta-1a | 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, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition; AND  Patient must be ambulatory (without assistance or support).  Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7695 |
| C7699 | P7699 | CN7699 | 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 7699 |
| C7714 | P7714 | CN7714 | Alemtuzumab | 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 7714 |
| C7777 | P7777 | CN7777 | Infliximab | Complex refractory Fistulising Crohn disease  Balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); or  Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); or  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment). | Compliance with Authority Required procedures |
| C7781 | P7781 | CN7781 | Montelukast | Asthma  Prevention of condition  The condition must be exercise-induced; AND  The treatment must be as an alternative to adding salmeterol xinafoate; or  The treatment must be an alternative to adding formoterol fumarate; AND  The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid; AND  Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms;  Patient must be aged 6 to 14 years inclusive. | Compliance with Authority Required procedures - Streamlined Authority Code 7781 |
| C7789 | P7789 | CN7789 | Perampanel | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition;  Patient must be aged 12 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 7789 |
| C7798 | P7798 | CN7798 | Aclidinium with formoterol  Indacaterol with glycopyrronium  Tiotropium with olodaterol  Umeclidinium with vilanterol | Chronic obstructive pulmonary disease (COPD)  Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA). or  Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA). or  Patient must have been stabilised on a combination of a LAMA and a LABA. | Compliance with Authority Required procedures - Streamlined Authority Code 7798 |
| C7815 | P7815 | CN7815 | Perampanel | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures  Initial treatment  Must be treated by a neurologist; AND  The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs; AND  The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug; AND  The treatment must be for dose titration purposes;  Patient must be aged 12 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 7815 |
| 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);  Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive. | Compliance with Authority Required procedures - Streamlined Authority Code 7876 |
| 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 |
| C7893 | P7893 | CN7893 | Quetiapine | Bipolar I disorder  The treatment must be maintenance therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 7893 |
| C7898 | P7898 | CN7898 | Fluconazole | Fungal infection  The condition must be serious or life-threatening. | Compliance with Authority Required procedures - Streamlined Authority Code 7898 |
| C7916 | P7916 | CN7916 | Quetiapine | Schizophrenia | Compliance with Authority Required procedures - Streamlined Authority Code 7916 |
| 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 |
| C7934 | P7934 | CN7934 | Fluconazole | Fungal infection  The condition must be serious or life-threatening; AND  Patient must be unable to take a solid dose form of fluconazole. | Compliance with Authority Required procedures - Streamlined Authority Code 7934 |
| 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  The treatment must be in combination with obinutuzumab; AND  The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 7944 |
| C7957 | P7957 | CN7957 | Ezetimibe and rosuvastatin  Ezetimibe with atorvastatin  Ezetimibe with simvastatin | Hypercholesterolaemia  The treatment must be in conjunction with dietary therapy and exercise; AND  Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND  Patient must have coronary heart disease. or  Patient must have cerebrovascular disease. or  Patient must have peripheral vascular disease. or  Patient must have diabetes mellitus with microalbuminuria. or  Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or  Patient must have diabetes mellitus and be aged 60 years or more. or  Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or  Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or  Patient must have heterozygous familial hypercholesterolaemia.  Patient must have homozygous familial hypercholesterolaemia. or  Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or  Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.  The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.  The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.  Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. | Compliance with Authority Required procedures - Streamlined Authority Code 7957 |
| C7958 | P7958 | CN7958 | Ezetimibe and rosuvastatin  Ezetimibe with atorvastatin  Ezetimibe with simvastatin | Hypercholesterolaemia  The treatment must be in conjunction with dietary therapy and exercise; AND  Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND  Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; AND  Patient must have coronary heart disease. or  Patient must have cerebrovascular disease. or  Patient must have peripheral vascular disease. or  Patient must have diabetes mellitus with microalbuminuria. or  Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or  Patient must have diabetes mellitus and be aged 60 years or more. or  Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or  Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or  Patient must have heterozygous familial hypercholesterolaemia.  Patient must have homozygous familial hypercholesterolaemia. or  Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or  A clinically important product-related adverse event is defined as follows  (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or  (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or  (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.  Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.  The type and severity of the adverse event or contraindication must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7958 |
| C7966 | P7966 | CN7966 | Ezetimibe | Hypercholesterolaemia  Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; or  Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; or  Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated; AND  Patient must have coronary heart disease. or  Patient must have cerebrovascular disease. or  Patient must have peripheral vascular disease. or  Patient must have diabetes mellitus with microalbuminuria. or  Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or  Patient must have diabetes mellitus and be aged 60 years or more. or  Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or  Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or  Patient must have heterozygous familial hypercholesterolaemia.  Patient must have homozygous familial hypercholesterolaemia. or  Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or  A clinically important product-related adverse event is defined as follows  (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or  (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or  (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.  Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.  The type and severity of the adverse event or contraindication must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7966 |
| C7970 | P7970 | CN7970 | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 7970 |
| C7972 | P7972 | CN7972 | Bendamustine | Previously untreated stage III or IV mantle cell lymphoma  Induction treatment  The condition must be CD20 positive; AND  The treatment must be in combination with rituximab; AND  The condition must be previously untreated; AND  The condition must be symptomatic; AND  The treatment must be for induction treatment purposes only; AND  Patient must not receive more than 6 cycles (12 doses) of treatment under this restriction; AND  Patient must not be eligible for stem cell transplantation. | Compliance with Authority Required procedures - Streamlined Authority Code 7972 |
| C7979 | P7979 | CN7979 | 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. | Compliance with Authority Required procedures - Streamlined Authority Code 7979 |
| C7990 | P7990 | CN7990 | Ezetimibe | Hypercholesterolaemia  Patient must have homozygous sitosterolaemia. | Compliance with Authority Required procedures - Streamlined Authority Code 7990 |
| C7996 | P7996 | CN7996 | Ezetimibe | Hypercholesterolaemia  The treatment must be in conjunction with dietary therapy and exercise; AND  The treatment must be co-administered with an HMG CoA reductase inhibitor (statin); AND  Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin); AND  Patient must have coronary heart disease. or  Patient must have cerebrovascular disease. or  Patient must have peripheral vascular disease. or  Patient must have diabetes mellitus with microalbuminuria. or  Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus. or  Patient must have diabetes mellitus and be aged 60 years or more. or  Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years. or  Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years. or  Patient must have heterozygous familial hypercholesterolaemia.  Patient must have homozygous familial hypercholesterolaemia. or  Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018. or  Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.  The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.  The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.  Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females. | Compliance with Authority Required procedures - Streamlined Authority Code 7996 |
| C8161 | P8161 | CN8161 | Octreotide | Acromegaly  The condition must be controlled with octreotide immediate release injections; AND  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  The treatment must cease if IGF1 is not lower after 3 months of treatment; AND  The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.  In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Authority Required procedures - Streamlined Authority Code 8161 |
| C8165 | P8165 | CN8165 | 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 surgery and where radiotherapy is contraindicated; AND  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  The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND  The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.  In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Authority Required procedures - Streamlined Authority Code 8165 |
| C8183 | P8183 | CN8183 | Trifluridine with tipiracil | Metastatic colorectal cancer  Continuing treatment  Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition; AND  Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8183 |
| C8197 | P8197 | CN8197 | Octreotide | Acromegaly  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The condition must be controlled with octreotide immediate release injections; AND  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  The treatment must cease if IGF1 is not lower after 3 months of treatment; AND  The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.  In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Authority Required procedures - Streamlined Authority Code 8197 |
| C8198 | P8198 | CN8198 | Octreotide | Vasoactive intestinal peptide secreting tumour (VIPoma)  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  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 8198 |
| C8208 | P8208 | CN8208 | Octreotide | Functional carcinoid tumour  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  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 8208 |
| C8214 | P8214 | CN8214 | Dolutegravir with rilpivirine | HIV infection  Initial treatment  Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8214 |
| C8226 | P8226 | CN8226 | Dolutegravir with rilpivirine | HIV infection  Continuing treatment  Patient must have previously received PBS-subsidised therapy with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8226 |
| C8262 | P8262 | CN8262 | Everolimus | Refractory seizures associated with tuberous sclerosis complex  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have maintained a response to the PBS-subsidised treatment with this drug for this condition; AND  The treatment must be in combination with at least one anti-epileptic drug; AND  Patient must not be a candidate for curative surgery. | Compliance with Authority Required procedures - Streamlined Authority Code 8262 |
| C8263 | P8263 | CN8263 | Everolimus | Refractory seizures associated with tuberous sclerosis complex  Initial treatment  Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC); AND  Patient must be experiencing a minimum of two partial-onset seizures per week; AND  The condition must have failed to be controlled satisfactorily at stable doses of at least two anti-epileptic drugs; AND  The treatment must be in combination with at least one anti-epileptic drug; AND  Patient must not be a candidate for curative surgery;  Patient must be at least 2 years of age. | Compliance with Authority Required procedures |
| C8288 | P8288 | CN8288 | Tolvaptan | Autosomal dominant polycystic kidney disease (ADPKD)  Continuing treatment  Must be treated by a nephrologist or in consultation with a nephrologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73m2; AND  Patient must not have had a kidney transplant. | Compliance with Authority Required procedures - Streamlined Authority Code 8288 |
| C8296 | P8296 | CN8296 | Infliximab | Severe chronic plaque psoriasis  Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply  Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| 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 haemopoieisis; 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  The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine); AND  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);  Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive. | Compliance with Authority Required procedures - Streamlined Authority Code 8544 |
| C8555 | P8555 | CN8555 | Ipilimumab | Stage IV clear cell variant renal cell carcinoma (RCC)  Induction treatment  The condition must not have previously been treated; AND  The condition must be classified as intermediate to poor risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC); AND  Patient must have a WHO performance status of 2 or less; AND  The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.  Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 8555 |
| C8584 | P8584 | CN8584 | Lenvatinib | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  Continuing treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not develop disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8584 |
| C8585 | P8585 | CN8585 | Guanfacine | Attention deficit hyperactivity disorder  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine). | Compliance with Authority Required procedures - Streamlined Authority Code 8585 |
| C8588 | P8588 | CN8588 | Axitinib | Stage IV clear cell variant renal cell carcinoma (RCC)  Initial treatment  Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND  Patient must have a WHO performance status of 2 or less; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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.  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 |
| C8606 | P8606 | CN8606 | Tiotropium | Severe asthma  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  Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND  Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; or  Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition; AND  The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated;  Patient must be aged 6 to 17 years inclusive.  Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative | Compliance with Authority Required procedures - Streamlined Authority Code 8606 |
| C8617 | P8617 | CN8617 | Sorafenib | Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma  Continuing treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not develop disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8617 |
| C8621 | P8621 | CN8621 | Sorafenib | Stage IV clear cell variant renal cell carcinoma (RCC)  Initial treatment  Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND  Patient must have a WHO performance status of 2 or less; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  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.  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 |
| C8622 | P8622 | CN8622 | Everolimus | Stage IV clear cell variant renal cell carcinoma (RCC)  Initial treatment  Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor; AND  Patient must have a WHO performance status of 2 or less; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.  Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus. | Compliance with Authority Required procedures |
| C8624 | P8624 | CN8624 | Safinamide | Parkinson disease  The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. |  |
| C8662 | P8662 | CN8662 | Etanercept | Severe active rheumatoid arthritis  Continuing treatment - balance of supply  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C8667 | P8667 | CN8667 | Filgrastim | 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 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  The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 8672 |
| C8673 | 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 |
| C8692 | P8692 | CN8692 | Etanercept | Severe active rheumatoid arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.  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 provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
| 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  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must be ambulatory; or  Patient must not be ambulatory, and must be able to either use upper limbs or to swallow; AND  Patient must not have undergone a tracheostomy; AND  Patient must not have experienced respiratory failure. | Compliance with Authority Required procedures |
| C8770 | P8770 | CN8770 | Lacosamide | Intractable partial epileptic seizures  Initial treatment  Must be treated by a neurologist; AND  The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents. | Compliance with Authority Required procedures - Streamlined Authority Code 8770 |
| 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 |
| C8777 | P8777 | CN8777 | Esomeprazole | Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion  Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor. | Compliance with Authority Required procedures |
| C8778 | P8778 | CN8778 | Esomeprazole | Scleroderma oesophagus  Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor. | Compliance with Authority Required procedures |
| C8780 | P8780 | CN8780 | Esomeprazole  Lansoprazole  Omeprazole  Pantoprazole  Rabeprazole | Scleroderma oesophagus | Compliance with Authority Required procedures - Streamlined Authority Code 8780 |
| C8813 | P8813 | CN8813 | Lacosamide | Intractable partial epileptic seizures  Initial treatment  Must be treated by a neurologist; AND  The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent; AND  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents; AND  The treatment must be for dose titration purposes. | Compliance with Authority Required procedures - Streamlined Authority Code 8813 |
| C8815 | P8815 | CN8815 | Lacosamide | Intractable partial epileptic seizures  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 8815 |
| 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;  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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C8831 | P8831 | CN8831 | Secukinumab | Severe chronic plaque psoriasis  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  Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C8839 | P8839 | CN8839 | Etanercept | Severe chronic plaque psoriasis  Subsequent continuing treatment, whole body  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (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.  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.  The most recent PASI assessment must be no more than 1 month old at the time of application.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C8842 | P8842 | CN8842 | Etanercept | Severe chronic plaque psoriasis  First continuing treatment, Face, hand, foot  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 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.  The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.  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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C8844 | P8844 | CN8844 | Infliximab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Whole body  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 8844 |
| C8866 | P8866 | CN8866 | Omeprazole  Pantoprazole | Zollinger-Ellison syndrome | Compliance with Authority Required procedures - Streamlined Authority Code 8866 |
| C8873 | P8873 | CN8873 | Etanercept | Severe chronic plaque psoriasis  Subsequent continuing treatment, Face, hand, foot  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (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.  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.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  The most recent PASI assessment must be no more than 1 month old at the time of application.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| 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 after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions; AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C8879 | P8879 | CN8879 | Etanercept | Severe chronic plaque psoriasis  Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply  Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Must be treated by a dermatologist. | Compliance with Authority Required procedures |
| C8881 | P8881 | CN8881 | Infliximab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Face, hand, foot  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.  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.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  The most recent PASI assessment must be no more than 1 month old at the time of application.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C8883 | P8883 | CN8883 | Infliximab | Severe chronic plaque psoriasis  First continuing treatment, Face, hand, foot  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 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.  The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.  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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C8887 | P8887 | CN8887 | Etanercept | Severe chronic plaque psoriasis  Subsequent continuing treatment, whole body  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 8887 |
| C8891 | P8891 | CN8891 | Ustekinumab | 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;  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.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed 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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C8892 | P8892 | CN8892 | Ixekizumab  Secukinumab | Severe chronic plaque psoriasis  Continuing treatment, Face, hand, foot  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 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.  The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.  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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| 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 syndrome. or  Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation. | Compliance with Authority Required procedures - Streamlined Authority Code 8921 |
| 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 |
| C8940 | P8940 | CN8940 | Infliximab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Face, hand, foot  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 8940 |
| C8941 | P8941 | CN8941 | Infliximab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Whole body  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.  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.  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.  Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.  The most recent PASI assessment must be no more than 1 month old at the time of application.  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C8947 | P8947 | CN8947 | Avelumab | Stage IV (metastatic) Merkel Cell Carcinoma  Initial treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  The treatment must not exceed a total of 9 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 8947 |
| C8955 | P8955 | CN8955 | Etanercept | Severe chronic plaque psoriasis  Subsequent continuing treatment, face, hand, foot  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 8955 |
| C8962 | P8962 | CN8962 | Infliximab | Severe chronic plaque psoriasis  First continuing treatment, Whole body  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.  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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C8987 | P8987 | CN8987 | Ustekinumab | Severe chronic plaque psoriasis  Continuing treatment, Face, hand, foot  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 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.  The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.  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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| 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 |
| C9032 | P9032 | CN9032 | Ursodeoxycholic acid | Primary biliary cholangitis (previously known as Primary biliary cirrhosis) | Compliance with Authority Required procedures - Streamlined Authority Code 9032 |
| C9034 | P9034 | CN9034 | 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 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);  Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive. | Compliance with Authority Required procedures - Streamlined Authority Code 9034 |
| C9041 | P9041 | CN9041 | Pegvisomant | Acromegaly  Initial treatment  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN); AND  The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information; AND  The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.  Somatostatin analogues include octreotide, lanreotide and pasireotide  Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as  1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR  2) IGF-1 level is greater than the age- and sex-adjusted ULN.  If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.  If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.  In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.  Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).  Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.  The authority application must be made in writing and must include  a) two completed authority prescription forms ; and  b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and  c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and  d) a recent result of the IGF-1 level and the date of assessment ; and  e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide | Compliance with Written Authority Required procedures |
| C9063 | P9063 | CN9063 | Certolizumab pegol  Golimumab  Secukinumab  Ustekinumab | Severe psoriatic arthritis  Continuing treatment - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
| C9064 | P9064 | CN9064 | Adalimumab  Etanercept  Golimumab  Secukinumab  Tofacitinib  Upadacitinib | Severe psoriatic arthritis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
| C9065 | P9065 | CN9065 | Infliximab | Severe psoriatic arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.  Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, 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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9067 | P9067 | CN9067 | Infliximab | Severe psoriatic arthritis  First continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.  Up to a maximum of 2 repeats will be authorised.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9068 | P9068 | CN9068 | Infliximab | Severe psoriatic arthritis  Continuing treatment - balance of supply  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C9069 | P9069 | CN9069 | Golimumab  Secukinumab | Severe psoriatic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9073 | P9073 | CN9073 | Certolizumab pegol | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 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.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9074 | P9074 | CN9074 | Certolizumab pegol | Severe psoriatic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction;  Patient must be aged 18 years or older.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9078 | P9078 | CN9078 | Secukinumab | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9081 | P9081 | CN9081 | Etanercept | Severe psoriatic arthritis  Continuing treatment - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
| C9088 | P9088 | CN9088 | Pasireotide | Acromegaly  Initial treatment  Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mlU/L; or  Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN); AND  The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information; AND  The treatment must not be given concomitantly with PBS-subsidised pegvisomant;  Patient must be aged 18 years or older.  If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.  If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.  Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as  1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR  2) IGF-1 level is greater than the age- and sex-adjusted ULN.  In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.  Biochemical evidence of remission is defined as  1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mlU/L; OR  2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)  The authority application must be made in writing and must include  a) a completed authority prescription form; and  b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and  c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and  d) a recent result of GH or IGF-1 levels must be provided. | Compliance with Written Authority Required procedures |
| C9089 | P9089 | CN9089 | Pasireotide | Acromegaly  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must not be given concomitantly with PBS-subsidised pegvisomant;  Patient must be aged 18 years or older.  In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.  Biochemical evidence of remission is defined as  1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mlU/L; OR  2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)  In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval. | Compliance with Authority Required procedures |
| C9105 | P9105 | CN9105 | Certolizumab pegol  Golimumab  Secukinumab | Severe psoriatic arthritis  Continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9111 | P9111 | CN9111 | Infliximab | Severe psoriatic arthritis  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 rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 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 22 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 22 weeks treatment; AND  The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C9116 | P9116 | CN9116 | Ustekinumab | Severe psoriatic arthritis  Continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9122 | P9122 | CN9122 | Ustekinumab | Severe psoriatic arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND  Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or  Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.  Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and  either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list of major joints  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9123 | P9123 | CN9123 | Etanercept | Severe psoriatic arthritis  First continuing treatment  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  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.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9140 | P9140 | CN9140 | Etanercept | Severe psoriatic arthritis  Subsequent continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, 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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9153 | P9153 | CN9153 | Golimumab | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9155 | P9155 | CN9155 | Golimumab  Secukinumab | Severe psoriatic arthritis  Initial treatment - Initial 1 (new patient)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND  Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or  Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.  Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.  The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and  either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list of major joints  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9156 | P9156 | CN9156 | Etanercept | Severe psoriatic arthritis  Subsequent continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 9156 |
| C9160 | P9160 | CN9160 | Ustekinumab | Severe psoriatic arthritis  Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in 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 rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; or  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 5 years) restriction to complete 28 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; AND  The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C9162 | P9162 | CN9162 | Etanercept | Severe chronic plaque psoriasis  First continuing treatment, Whole body  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9172 | P9172 | CN9172 | Guselkumab  Ixekizumab | Severe psoriatic arthritis  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 rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment; AND  The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C9175 | P9175 | CN9175 | Ustekinumab | Severe psoriatic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9176 | P9176 | CN9176 | Ustekinumab | Severe psoriatic arthritis  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or  The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND  The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND  Patient must not receive more than 28 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9180 | P9180 | CN9180 | Tocilizumab | Active giant cell arteritis  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. | Compliance with 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 application  an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and  either  (a) an active joint count of at least 20 active (swollen and tender) joints; or  (b) at least 4 active joints from the following list of major joints  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.  The authority application must be made in writing and must include  (1) a completed authority prescription form(s); and  (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9185 | P9185 | CN9185 | Certolizumab pegol | Severe psoriatic arthritis  Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment; AND  The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. | Compliance with Authority Required procedures |
| C9188 | P9188 | CN9188 | Infliximab | Severe psoriatic arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 9188 |
| C9203 | P9203 | CN9203 | Imatinib | Acute lymphoblastic leukaemia  Initial treatment  Patient must be newly diagnosed; AND  The condition must be expressing the Philadelphia chromosome; or  The condition must have the transcript BCR-ABL; AND  The treatment must be for induction and consolidation therapy; AND  The treatment must be in combination with chemotherapy or corticosteroids; AND  Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition. or  Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.  A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C9204 | P9204 | CN9204 | Imatinib | Aggressive systemic mastocytosis with eosinophilia  Initial treatment  Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene; AND  Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; or  Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea); AND  The treatment must not exceed a maximum dose of 400 mg per day.  A pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.  The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C9206 | P9206 | CN9206 | Imatinib | Aggressive systemic mastocytosis with eosinophilia  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have confirmed evidence of carrying the FIP1L1-PDGFRA fusion gene; 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 9206 |
| C9207 | P9207 | CN9207 | Imatinib | Acute lymphoblastic leukaemia  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; or  Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; AND  The condition must be expressing the Philadelphia chromosome; or  The condition must have the transcript BCR-ABL; AND  The treatment must be for maintenance of first complete remission; AND  The treatment must be in combination with chemotherapy or corticosteroids.  Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting. | Compliance with Authority Required procedures - Streamlined Authority Code 9207 |
| C9209 | P9209 | CN9209 | Imatinib | Dermatofibrosarcoma protuberans  Continuing treatment  The condition must be unresectable; or  The condition must be locally recurrent; or  The condition must be metastatic; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated a response to the PBS-subsidised treatment; AND  The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND  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. | Compliance with Authority Required procedures - Streamlined Authority Code 9209 |
| 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 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 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 surgery and where radiotherapy is contraindicated; AND  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  The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily; AND  The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.  In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Authority Required procedures - Streamlined Authority Code 9233 |
| C9234 | P9234 | CN9234 | Pamidronic acid | Hypercalcaemia of malignancy  Patient must have a malignancy refractory to anti-neoplastic therapy. | Compliance with Authority Required procedures - Streamlined Authority Code 9234 |
| C9235 | P9235 | CN9235 | 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 9235 |
| C9238 | P9238 | CN9238 | Imatinib | Gastrointestinal stromal tumour  Initial treatment  The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST); AND  Patient must be at high risk of recurrence following complete surgical resection of primary GIST; AND  The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining; AND  The treatment must not exceed a dose of 400 mg per day for a period of 36 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. | Compliance with Authority Required procedures |
| C9240 | P9240 | CN9240 | Imatinib | 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. | Compliance with Authority Required procedures |
| C9243 | P9243 | CN9243 | Imatinib | 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 9243 |
| 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 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. | Compliance with Authority Required procedures - Streamlined Authority 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 haemopoieisis; 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  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 surgery and where radiotherapy is contraindicated; AND  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  The treatment must cease if IGF1 is not lower after 3 months of treatment; AND  The treatment must not be given concomitantly with PBS-subsidised pegvisomant.  In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission. | Compliance with Authority Required procedures - Streamlined Authority Code 9261 |
| C9262 | P9262 | CN9262 | Octreotide | Acromegaly  The condition must be controlled with octreotide immediate release injections; AND  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  The treatment must cease if IGF1 is not lower after 3 months of treatment; AND  The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.  In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission | Compliance with Authority Required procedures - Streamlined Authority Code 9262 |
| C9267 | P9267 | CN9267 | 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 9267 |
| 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-PDGFRA 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-PDGFRA fusion gene, a full blood examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C9276 | P9276 | 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  The treatment must not exceed a maximum dose of 400 mg per day.  A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C9278 | P9278 | CN9278 | Imatinib | Gastrointestinal stromal tumour  Continuing treatment  The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST); AND  Patient must be at high risk of recurrence following complete surgical resection of primary GIST; AND  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  Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST. | Compliance with Authority Required procedures - Streamlined Authority Code 9278 |
| C9286 | P9286 | CN9286 | 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 9286 |
| C9287 | P9287 | CN9287 | 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 9287 |
| C9288 | P9288 | CN9288 | 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 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 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  The treatment must not exceed a maximum dose of 400 mg per day.  A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9296 |
| C9298 | P9298 | CN9298 | Nivolumab | Unresectable Stage III or Stage IV malignant melanoma  Continuing treatment  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must have previously been issued with an authority prescription for this drug for this condition; AND  Patient must have stable or responding disease.  Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen. | Compliance with Authority Required procedures - Streamlined Authority Code 9298 |
| C9299 | P9299 | CN9299 | Nivolumab | Stage IV clear cell variant renal cell carcinoma (RCC)  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while being treated with this drug for this condition; AND  The treatment must be the sole PBS-subsidised therapy for this 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. | Compliance with Authority Required procedures - Streamlined Authority Code 9299 |
| C9302 | P9302 | CN9302 | 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 9302 |
| 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 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 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 |
| C9316 | P9316 | CN9316 | Valganciclovir | Cytomegalovirus infection and disease  Prophylaxis  Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9316 |
| 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 dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.  A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347 472-80.)  A pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining must be documented in the patient's medical records.  Details of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease must be documented in the patient's medical records.  Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C9321 | P9321 | CN9321 | Nivolumab | Stage IV clear cell variant renal cell carcinoma (RCC)  Maintenance treatment  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  The treatment must be as monotherapy for this condition; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug 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.  The patient's body weight must be documented in the patient's medical records at the time treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 9321 |
| 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  Must be treated by a geriatrician; AND  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  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 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  Patient must not have established severe contracture in the limb to be treated; AND  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;  Patient must be aged 18 years or older.  Standard management includes physiotherapy and/or oral spasticity agents. | Compliance with Authority Required procedures - Streamlined Authority Code 9334 |
| C9335 | P9335 | CN9335 | Pamidronic acid | Multiple myeloma | Compliance with Authority Required procedures - Streamlined Authority Code 9335 |
| C9349 | P9349 | CN9349 | Trastuzumab | Metastatic (Stage IV) HER2 positive breast cancer  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.  Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, a new loading dose may be required. | Compliance with Authority Required procedures - Streamlined Authority Code 9349 |
| C9353 | P9353 | CN9353 | Trastuzumab | Metastatic (Stage IV) HER2 positive breast cancer  Initial treatment  Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion; AND  The treatment must not be in combination with nab-paclitaxel; 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.  Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 9353 |
| C9360 | P9360 | CN9360 | Lapatinib | Metastatic (Stage IV) HER2 positive breast cancer  Continuing treatment  Patient must have received an initial authority prescription for this drug for this condition; AND  The treatment must be in combination with capecitabine; AND  Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND  The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition; AND  The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.  A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.  The treatment must not exceed a lifetime total of one continuous course. | Compliance with Authority Required procedures - Streamlined Authority Code 9360 |
| C9367 | P9367 | CN9367 | Dasatinib | Acute lymphoblastic leukaemia  Initial treatment  Patient must be newly diagnosed; AND  The condition must be expressing the Philadelphia chromosome; or  The condition must have the transcript BCR-ABL; AND  The treatment must be for induction and consolidation therapy; AND  The treatment must be in combination with chemotherapy or corticosteroids; AND  Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition. or  Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.  The authority application must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and  (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided). | Compliance with Written Authority Required procedures |
| C9369 | P9369 | CN9369 | Blinatumomab | Acute lymphoblastic leukaemia  Consolidation treatment  Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND  Patient must have achieved a complete remission; or  Patient must have achieved a complete remission with partial haematological recovery; AND  The treatment must not be more than 3 treatment cycles under this restriction in a lifetime; AND  Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. | Compliance with Authority Required procedures |
| C9377 | P9377 | CN9377 | Etanercept | Severe active juvenile idiopathic arthritis  Continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C9380 | P9380 | CN9380 | Etanercept  Tocilizumab | Severe active juvenile idiopathic arthritis  Continuing Treatment - balance of supply  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |
| C9386 | P9386 | CN9386 | Adalimumab  Etanercept  Tocilizumab | Severe active juvenile idiopathic arthritis  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  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received insufficient therapy with this drug for this condition under the 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 24 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 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. | Compliance with Authority Required procedures |
| C9388 | P9388 | CN9388 | Etanercept | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  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.  A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| 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  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count must be no more than 4 weeks old at the time of this application.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9404 | P9404 | CN9404 | Ganciclovir | Cytomegalovirus disease  Prophylaxis  Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9404 |
| C9407 | P9407 | CN9407 | 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  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count must be no more than 4 weeks old at the time of this application.  At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9417 | P9417 | CN9417 | Etanercept  Tocilizumab  Tofacitinib | 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 than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply  Must be treated by a paediatric rheumatologist; or  Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| 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 treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
| C9431 | P9431 | CN9431 | Certolizumab pegol  Golimumab  Ixekizumab  Secukinumab  Tofacitinib  Upadacitinib | Ankylosing spondylitis  Continuing treatment - balance of supply  Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND  The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
| C9443 | P9443 | CN9443 | Mesalazine | Crohn disease |  |
| C9444 | P9444 | CN9444 | Mesalazine | Ulcerative colitis |  |
| C9462 | P9462 | CN9462 | Trastuzumab | Metastatic (Stage IV) HER2 positive breast cancer  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. | Compliance with Authority Required procedures - Streamlined Authority Code 9462 |
| C9465 | P9465 | CN9465 | Ponatinib | Acute lymphoblastic leukaemia  Continuing treatment  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. | Compliance with Authority Required procedures |
| C9468 | P9468 | CN9468 | Dasatinib | Acute lymphoblastic leukaemia  Initial treatment  The condition must be expressing the Philadelphia chromosome; or  The condition must have the transcript BCR-ABL; AND  Patient must have failed treatment with chemotherapy; AND  Patient must have failed treatment with imatinib; AND  Patient must have failed an allogeneic haemopoeitic stem cell transplantation if applicable.  Failure of treatment is defined as either  (i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;  (ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;  (iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.  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 expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.  The authority application must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and  (c) 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. The date of the relevant pathology report(s) need(s) to be provided. | Compliance with Written Authority Required procedures |
| C9469 | P9469 | CN9469 | Dasatinib | Acute lymphoblastic leukaemia  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; or  Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition; AND  The condition must be expressing the Philadelphia chromosome; or  The condition must have the transcript BCR-ABL; AND  The treatment must be for maintenance of first complete remission; AND  The treatment must be in combination with chemotherapy or corticosteroids.  Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting. | Compliance with Authority Required procedures |
| C9470 | P9470 | CN9470 | Inotuzumab ozogamicin | Acute lymphoblastic leukaemia  Induction treatment  The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND  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 m2 for the first dose of a treatment cycle (Day 1), and 0.5mg per m2 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. | Compliance with Written Authority Required procedures |
| C9472 | P9472 | CN9472 | Infliximab | Severe psoriatic arthritis  Subsequent continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  either of the following  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.  The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 9472 |
| C9473 | P9473 | CN9473 | Etanercept | 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  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  All measures of joint count must be no more than 4 weeks old at the time of this application.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| 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 than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply  Must be treated by a paediatric rheumatologist; or  Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; AND  Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; or  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  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  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. or  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. | Compliance with Authority Required procedures |
| C9478 | P9478 | CN9478 | Tocilizumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  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.  A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C9488 | P9488 | CN9488 | 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 9488 |
| C9489 | P9489 | CN9489 | 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 9489 |
| C9490 | P9490 | CN9490 | Clozapine | Schizophrenia  Initial treatment  Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient; AND  Patient must be non-responsive to other neuroleptic agents. or  Patient must be intolerant of other neuroleptic agents.  Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.  The name of the consulting psychiatrist should be included in the patient's medical records.  A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised. | Compliance with Authority Required procedures - Streamlined Authority Code 9490 |
| C9494 | P9494 | CN9494 | Tocilizumab | Severe active juvenile idiopathic arthritis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  Patient must not receive more than 16 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  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.  A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C9495 | P9495 | CN9495 | Tocilizumab | Severe active juvenile idiopathic arthritis  Continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.  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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C9519 | P9519 | CN9519 | Blinatumomab | Acute lymphoblastic leukaemia  Induction treatment - balance of supply  The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND  The condition must not be present in the central nervous system or testis; AND  Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND  Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime.  According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended.  An amount of 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. | Compliance with Authority Required procedures |
| 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 antispastic agents; AND  Patient must have chronic spasticity due to spinal cord disease. | Compliance with Authority Required procedures - Streamlined Authority 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 |
| C9526 | P9526 | CN9526 | Ganciclovir | Cytomegalovirus disease  Prophylaxis  Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease. | Compliance with Authority Required procedures - Streamlined Authority Code 9526 |
| 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.  Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | Compliance with Authority Required procedures - Streamlined Authority Code 9527 |
| 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  The condition must have the transcript BCR-ABL; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition as second-line therapy following treatment with imatinib; AND  The condition must not have progressed. | Compliance with Authority Required procedures |
| C9553 | P9553 | CN9553 | Tocilizumab | Severe active juvenile idiopathic arthritis  Continuing treatment  Must be treated by a rheumatologist; or  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;  AND either of the following  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%  (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.  The authority application must be made in writing and must include  (1) completed authority prescription form(s); and  (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.  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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
| C9559 | P9559 | CN9559 | Infliximab | 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 under the Initial 1 (new patient) restriction to complete 18 weeks treatment; or  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 5 years) restriction to complete 18 weeks treatment; or  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 5 years) restriction to complete 18 weeks treatment; AND  The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
| 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 in situ hybridisation results based on more than 6 copies of HER2 in the same tumour tissue sample; AND  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  Patient must commence treatment in combination with platinum based chemotherapy and capecitabine; or  Patient must commence treatment in combination with platinum based chemotherapy and 5 fluorouracil; AND  Patient must not have previously received this drug for this condition; AND  Patient must not have received prior chemotherapy for this condition; AND  Patient must have a WHO performance status of 2 or less; 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.  Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 9573 |
| C9584 | P9584 | CN9584 | Infliximab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Face, hand, foot  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 9584 |
| C9589 | P9589 | CN9589 | Alemtuzumab | 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  Patient must not receive more than one PBS-subsidised treatment per year; 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 9589 |
| 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  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. | Compliance with Authority Required procedures - Streamlined Authority Code 9592 |
| C9593 | P9593 | CN9593 | Mannitol | Cystic fibrosis  The treatment must be in combination with dornase alfa; AND  Patient must be inadequately responsive to dornase alfa; AND  Patient must have trialled hypertonic saline for this condition;  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.  Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | Compliance with Authority Required procedures - Streamlined Authority Code 9593 |
| C9601 | P9601 | CN9601 | Inotuzumab ozogamicin | Acute lymphoblastic leukaemia  Consolidation treatment  Patient must have previously received PBS-subsidised induction treatment with this drug for this condition; AND  Patient must have achieved a complete remission; or  Patient must have achieved a complete remission with partial haematological recovery; AND  The treatment must not be more than 5 treatment cycles under this restriction in a lifetime; AND  Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.  This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.  The treatment must not exceed 0.5mg per m2 for all doses within a treatment cycle  Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime. | Compliance with Authority Required procedures |
| C9602 | P9602 | CN9602 | Infliximab | Severe chronic plaque psoriasis  Subsequent continuing treatment, Whole body  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction;  Patient must be aged 18 years or older;  Must be treated by a dermatologist.  An adequate response to treatment is defined as  A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 9602 |
| C9603 | P9603 | CN9603 | Peginterferon alfa-2a | Chronic hepatitis C infection  Must be treated in an accredited treatment centre;  Patient must be aged 18 years or older;  Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age;  Patient must have compensated liver disease; AND  Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C; AND  Patient must have a contraindication to ribavirin; AND  The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop; AND  The treatment must be limited to a maximum duration of 48 weeks.  Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9603 |
| C9604 | P9604 | CN9604 | Azithromycin | 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 9604 |
| C9606 | P9606 | CN9606 | 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 9606 |
| C9614 | P9614 | CN9614 | Ponatinib | Acute lymphoblastic leukaemia  Initial treatment  The condition must be expressing the Philadelphia chromosome; or  The condition must have the transcript BCR-ABL; AND  Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition. or  Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal.  Failure of treatment with dasatinib is defined as either  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.  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.  The authority application must be made in writing and must include  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 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 | Compliance with Written Authority Required procedures |
| 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  (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 intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use. | Compliance with Authority Required procedures - Streamlined Authority Code 9624 |
| C9625 | P9625 | CN9625 | Certolizumab pegol | 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 18 to 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment; AND  The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions; AND  Must be treated by a rheumatologist. or  Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. | Compliance with Authority Required procedures |
| C9632 | P9632 | CN9632 | Infliximab | Acute severe ulcerative colitis  Must be treated by a gastroenterologist; or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology]; AND  Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application; AND  Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following:   (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; or  Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below; AND  Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital;  Patient must be 6 years of age or older.  For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where  (i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L  (ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.  For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.  At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.  Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.  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 9632 |
| C9635 | P9635 | CN9635 | 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 9635 |
| C9636 | P9636 | CN9636 | Alemtuzumab | 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 9636 |
| C9637 | P9637 | CN9637 | 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 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 |
| C9655 | P9655 | CN9655 | Ustekinumab | Severe Crohn disease  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND  The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction;  Patient must be aged 18 years or older.  Applications for authorisation must be made in writing and must include  (a) two completed authority prescription forms; and  (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following  (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or  (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and  (iii) the date of clinical assessment; and  (iv) the details of prior biological medicine treatment including the details of date and duration of treatment.  Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.  A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.  Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.  Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.  To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.  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 or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9656 | P9656 | CN9656 | Ustekinumab | Severe Crohn disease  Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND  Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; or  Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; or  Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND  Patient must have evidence of intestinal inflammation; or  Patient must be assessed clinically as being in a high faecal output state; or  Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND  The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction;  Patient must be aged 18 years or older.  Applications for authorisation must be made in writing and must include  (a) two completed authority prescription forms; and  (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and  (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and  (iii) the date of the most recent clinical assessment.  Evidence of intestinal inflammation includes  (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or  (ii) faeces higher than normal lactoferrin or calprotectin level; or  (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.  Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.  A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.  Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.  Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.  Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9657 | P9657 | CN9657 | Ustekinumab | Severe Crohn disease  Continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or  Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by:   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following  (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or  (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and  (iii) the date of clinical assessment.  All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.  An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.  The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.  Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.  Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months. | Compliance with Written Authority Required procedures |
| C9668 | P9668 | CN9668 | Infliximab | Moderate to severe Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND  Patient must have a total PCDAI score of 30 points or less; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive.  The PCDAI assessment must be no more than 1 month old at the time of prescribing.  The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy.  Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response. | Compliance with Authority Required procedures - Streamlined Authority Code 9668 |
| C9669 | P9669 | CN9669 | Infliximab | Moderate to severe Crohn disease  Balance of supply for paediatric patient  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); or  Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment. or  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment. | Compliance with Authority Required procedures |
| C9677 | P9677 | CN9677 | Infliximab | Complex refractory Fistulising Crohn disease  Subsequent continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  Must be treated by a gastroenterologist (code 87). or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].  An adequate response is defined as  (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.  The most recent fistula assessment must be no more than 1 month old at the time of application.  Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised. | Compliance with Written Authority Required procedures |
| C9688 | P9688 | CN9688 | 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 9688 |
| C9689 | P9689 | CN9689 | Mycophenolic acid | Management of renal allograft rejection  Management (initiation, stabilisation and review of therapy)  Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9689 |
| C9690 | P9690 | CN9690 | Mycophenolic acid | Management of cardiac allograft rejection  Management (initiation, stabilisation and review of therapy )  Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9690 |
| C9691 | P9691 | CN9691 | Everolimus  Mycophenolic acid | Management of renal allograft rejection  Management (initiation, stabilisation and review of therapy)  Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9691 |
| C9692 | P9692 | CN9692 | Mycophenolic acid | Prophylaxis of renal allograft rejection  Management  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9692 |
| C9693 | P9693 | CN9693 | Everolimus  Mycophenolic acid | Management of cardiac allograft rejection  Management (initiation, stabilisation and review of therapy)  Patient must be receiving this drug for prophylaxis of cardiac allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9693 |
| 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 |
| C9697 | P9697 | CN9697 | Tacrolimus | Management of rejection in patients following organ or tissue transplantation  The treatment must be under the supervision and direction of a transplant unit; AND  The treatment must include initiation, stabilisation, and review of therapy as required. | Compliance with Authority Required procedures - Streamlined Authority Code 9697 |
| 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  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND  Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND  Patient must have a Mayo clinic score greater than or equal to 6; or  Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);  Patient must be aged 18 years or older.  Application for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and  (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.  A maximum 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.  All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.  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.  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.  Details of the accepted toxicities including severity can be found on the Department of Human Services website. | Compliance with Written Authority Required procedures |
| C9710 | P9710 | CN9710 | Ustekinumab | Severe Crohn disease  Initial treatment - Initial 1 (new patient)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)];  Patient must be aged 18 years or older;  Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND  Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND  Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; or  Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; or  Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND  The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction; AND  Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy. or  Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. or  Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.  Applications for authorisation must be made in writing and must include  (a) two completed authority prescription forms; and  (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and  (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and  (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and  (iv) the date of the most recent clinical assessment.  Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following  (a) patient must have evidence of intestinal inflammation;  (b) patient must be assessed clinically as being in a high faecal output state;  (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.  (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or  (ii) faeces higher than normal lactoferrin or calprotectin level; or  (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.  Evidence of intestinal inflammation includes  (i) blood higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or  (ii) faeces higher than normal lactoferrin or calprotectin level; or  (iii) diagnostic imaging demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.  Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.  A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.  Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.  Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.  All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment  If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.  If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.  Details of the accepted toxicities including severity can be found on the Department of Human Services website.  Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.  An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.  Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.  If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | Compliance with Written Authority Required procedures |
| C9711 | P9711 | CN9711 | Ustekinumab | Severe Crohn disease  Balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment. or  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment. | Compliance with Authority Required procedures |
| C9715 | P9715 | CN9715 | Adalimumab | 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)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or  Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND  The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. | Compliance with Authority Required procedures |
| C9719 | P9719 | CN9719 | Infliximab | Moderate to severe Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND  Patient must have a total PCDAI score of 30 points or less; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.  The PCDAI assessment must be no more than 1 month old at the time of application.  Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.  If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period. | Compliance with Written Authority Required procedures |
| C9721 | P9721 | CN9721 | Infliximab | Moderate to severe Crohn disease  First continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND  Patient must have a total PCDAI score of 30 points or less; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.  The PCDAI assessment must be no more than 1 month old at the time of application.  The application for first continuing treatment with this drug must include a PCDAI assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.  Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.  If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period. | Compliance with Written Authority Required procedures |
| C9732 | P9732 | CN9732 | Infliximab | Complex refractory Fistulising Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND  Patient must have demonstrated an adequate response to treatment with this drug.  An adequate response is defined as  (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  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.  Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response. | Compliance with Authority Required procedures - Streamlined Authority Code 9732 |
| C9738 | P9738 | CN9738 | Vedolizumab | Moderate to severe ulcerative colitis  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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); or  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; or  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment; AND  Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. | Compliance with Authority Required procedures |
| C9742 | P9742 | CN9742 | Ciclosporin | Severe active rheumatoid arthritis  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. | Compliance with Authority Required procedures - Streamlined Authority Code 9742 |
| 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 |
| C9751 | P9751 | CN9751 | Infliximab | Moderate to severe Crohn disease  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle; AND  The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction;  Patient must be aged 6 to 17 years inclusive.  Application for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following  (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and  (ii) details of prior biological medicine treatment including details of date and duration of treatment.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.  If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.  A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.  If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.  A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.  This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.  Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
| C9754 | P9754 | CN9754 | Infliximab | Moderate to severe ulcerative colitis  Balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); or  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment. or  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing 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  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 9762 |
| 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.  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.  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.  A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. | Compliance with Authority Required procedures |
| C9771 | P9771 | CN9771 | Vedolizumab | Severe Crohn disease  Balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); or  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; or  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment; AND  Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. | Compliance with Authority Required procedures |
| C9775 | P9775 | CN9775 | Infliximab | Moderate to severe Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; or  Must be treated by a paediatrician; or  Must be treated by a specialist paediatric gastroenterologist; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND  Patient must have a reduction in PCDAI Score by at least 15 points from baseline value; AND  Patient must have a total PCDAI score of 30 points or less; AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 6 to 17 years inclusive.  The PCDAI assessment must be no more than 1 month old at the time of prescribing.  The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy.  Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response. | Compliance with Authority Required procedures - Streamlined Authority Code 9775 |
| C9779 | P9779 | CN9779 | Infliximab | Severe Crohn disease  Balance of supply  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); 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 the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); or  Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; AND  The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment. or  The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment. | Compliance with Authority Required procedures |
| C9783 | P9783 | CN9783 | Infliximab | Complex refractory Fistulising Crohn disease  First continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug.  An adequate response is defined as  (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.  The most recent fistula assessment must be no more than 1 month old at the time of application.  The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.  Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.  A maximum of 24 weeks of treatment with this drug will be authorised under this restriction.  At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide for infusion*s* at a dose of 5 mg per kg eight weekly.  Up to a maximum of 2 repeats will be authorised. | Compliance with Written Authority Required procedures |
| C9787 | P9787 | CN9787 | Infliximab | Complex refractory Fistulising Crohn disease  Subsequent continuing treatment  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle; AND  Patient must have demonstrated an adequate response to treatment with this drug.  An adequate response is defined as  (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or  (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.  The measurement of response to the prior course of therapy must be documented in the patient's medical notes.  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.  Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response. | Compliance with Authority Required procedures - Streamlined Authority Code 9787 |
| C9803 | P9803 | CN9803 | Infliximab | Complex refractory Fistulising Crohn disease  Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.  Applications for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following  (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and  (ii) details of prior biological medicine treatment including details of date and duration of treatment.  The most recent fistula assessment must be no more than 1 month old at the time of application.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.  To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.  If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.  A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.  An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.  This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.  Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. | Compliance with Written Authority Required procedures |
| C9809 | P9809 | CN9809 | Mycophenolic acid | WHO Class III, IV or V lupus nephritis  Management  The condition must be proven by biopsy; AND  Must be treated by a nephrologist or in consultation with a nephrologist.  The name of the consulting nephrologist must be included in the patient medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 9809 |
| C9822 | P9822 | CN9822 | Golimumab | Moderate to severe ulcerative colitis  Initial treatment - Initial 1 (new patient)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND  Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or  Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or  Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND  Patient must have a Mayo clinic score greater than or equal to 6; or  Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score);  Patient must be aged 18 years or older.  Application for authorisation of initial treatment must be in writing and must include  (a) a completed authority prescription form; and  (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and  (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].  All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.  The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.  A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.  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.  If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.  An 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.  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.  Details of the accepted toxicities including severity can be found on the Department of Human Services website. | Compliance with Written Authority Required procedures |
| C9823 | P9823 | CN9823 | Golimumab | Moderate to severe ulcerative colitis  Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)  Must be treated by a gastroenterologist (code 87); or  Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or  Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND  Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND  Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle;  Patient must be aged 18 years or older.  Application for authorisation must be made in writing and must include  (a) a completed authority prescription form; and  (b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following  (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and  (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.  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.  An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.  Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy 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.  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.  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.  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. | Compliance with Written Authority Required procedures |
| C9828 | P9828 | CN9828 | Terbutaline | Bronchospasm  Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist. or  Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.  Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine. | Compliance with Authority Required procedures - Streamlined Authority Code 9828 |
| C9831 | P9831 | CN9831 | Ciclosporin | Management of transplant rejection  The treatment must be used by organ or tissue transplant recipients. | Compliance with Authority Required procedures - Streamlined Authority Code 9831 |
| C9914 | P9914 | CN9914 | Sirolimus | Management of renal allograft rejection  Management (initiation, stabilisation and review of therapy)  Patient must be receiving this drug for prophylaxis of renal allograft rejection; AND  The treatment must be under the supervision and direction of a transplant unit. | Compliance with Authority Required procedures - Streamlined Authority Code 9914 |
| C9919 | P9919 | CN9919 | Sodium phenylbutyrate | Urea cycle disorders  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 9919 |
| C9933 | P9933 | CN9933 | Risankizumab | Severe chronic plaque psoriasis  Continuing treatment, Whole body  Must be treated by a dermatologist; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| C9955 | P9955 | CN9955 | Risankizumab | Severe chronic plaque psoriasis  Continuing treatment, Face, hand, foot  Must be treated by a dermatologist; AND  Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND  Patient must have demonstrated an adequate response to treatment with this drug; AND  The treatment must be as systemic monotherapy (other than methotrexate); AND  Patient must not receive more than 24 weeks of treatment under this restriction;  Patient must be aged 18 years or older.  An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing  (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.  The authority application must be made in writing and must include  (a) a completed authority prescription form(s); and  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.  The most recent PASI assessment must be no more than 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.  The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.  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 under a new cycle under the Initial 3 treatment restriction. | Compliance with Written Authority Required procedures |
| 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 |