National Health (Listing of Pharmaceutical Benefits) Instrument 2024

PB 26 of 2024

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

National Health Act 1953

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This compilation is in 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: C4072–C9993)
Volume 6: Schedule 4 (Part 1: C10020–C12999)
Volume 7: Schedule 4 (Part 1: C13001–C15242, Part 2)
Volume 8: Schedules 5, 6 and Endnotes

Each volume has its own contents

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About this compilation

This compilation

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

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

Uncommenced amendments

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

Application, saving and transitional provisions for provisions and amendments

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

Editorial changes

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

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Schedule 4—Circumstances, purposes, 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	Compliance with Authority Required procedures -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				unit.	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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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)	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must have an inflammatory component; AND Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.	procedures - Streamlined Authority Code 4159
C4171	P4171	CN4171	Macrogol 3350	Constipation Patient must have malignant neoplasia.	
C4172	P4172	CN4172	Pregabalin	Neuropathic pain The condition must be refractory to treatment with other drugs.	Compliance with Authority Required procedures - Streamlined Authority Code 4172
C4173	P4173	CN4173	Macrogol 3350	Chronic constipation The condition must be inadequately controlled with first line interventions such as bulk-forming agents.	
C4177	P4177	CN4177	Macrogol 3350	Faecal impaction The condition must be inadequately controlled with first line interventions such as bulk-forming agents.	
C4179	P4179	CN4179	Macrogol 3350	Constipation Patient must be receiving palliative care.	
C4180	P4180	CN4180	Macrogol 3350	Constipation Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function; AND The condition must be unresponsive to other oral therapies.	
C4181	P4181	CN4181	Ciprofloxacin Ofloxacin	Bacterial keratitis Must be treated by an ophthalmologist or in consultation with an ophthalmologist.	Compliance with Authority Required procedures
C4190	P4190	CN4190	Rotigotine	Parkinson disease The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Phenylketonuria	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			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		
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	Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Initial treatment for up to 6 months	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			polyunsaturated fatty acids Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula	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.	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	Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Initial treatment for up to 6 months	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			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	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.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			polyunsaturated fatty acids Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides Amino acids-synthetic, formula		
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	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;	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			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	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.	
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	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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Latanoprost with timolol Travoprost with timolol		
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	Compliance with Authority Required procedures - Streamlined Authority Code 4349

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			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	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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 4363

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 4364

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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;	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			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		
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	Compliance with Authority Required procedures - Streamlined Authority Code 4423

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	HIV infection	Compliance with

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Atazanavir Atazanavir with cobicistat Dolutegravir Emtricitabine with tenofovir alafenamide Lamivudine Lamivudine with zidovudine Lopinavir with ritonavir Nevirapine Raltegravir Rilpivirine Ritonavir Zidovudine	Continuing Patient must have previously received PBS-subsidised therapy for HIV infection; AND The treatment must be in combination with other antiretroviral agents.	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	HIV infection Continuing Patient must have previously received PBS-subsidised therapy for HIV	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			tenofovir alafenamide Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat Tenofovir with emtricitabine and efavirenz	infection.	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	Compliance with Authority Required procedures - Streamlined Authority Code 4490

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Nevirapine Raltegravir Rilpivirine Ritonavir Zidovudine		
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	HIV infection Initial Patient must be antiretroviral treatment naive.	Compliance with Authority Required procedures - Streamlined Authority Code 4522

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Tenofovir with emtricitabine and efavirenz		
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.	Compliance with Authority Required procedures - Streamlined Authority Code 4524

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	

Clause 1

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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				unknown type.	
C4601	P4601	CN4601	Macrogol 3350	Faecal impaction The condition must be inadequately controlled with first line interventions such as bulk-forming agents.	
C4649	P4649	CN4649	Eribulin	Locally advanced or metastatic breast cancer Patient must have progressive disease; AND Patient must have failed at least two prior chemotherapeutic regimens for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 4649
C4651	P4651	CN4651	Triglycerides - medium chain, formula	Hyperlipoproteinaemia type 1	
C4652	P4652	CN4652	Triglycerides - medium chain, formula	Chylous ascites	
C4653	P4653	CN4653	Triglycerides - medium chain, formula	Chylothorax	
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	Compliance with Authority Required procedures - Streamlined Authority Code 4657

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				longer eligible for PBS-subsidised treatment with this drug.	
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.	Compliance with Authority Required procedures

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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			and carbohydrate	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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be unable to tolerate cisplatin. or Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.	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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be in combination with exemestane; Patient must not be pre-menopausal.	
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)	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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).	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 4908

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Urea cycle disorders	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Essential amino acids formula with minerals and vitamin c Essential amino acids formula with vitamins and minerals		
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	Compliance with Authority Required procedures - Streamlined Authority Code 4979

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 4991

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 4997

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				implantation confirmed by positive B-hCG measurement.	
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;	Compliance with Authority Required procedures - Streamlined Authority Code 5004

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Travoprost with timolol		
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have confirmed acute symptomatic pulmonary embolism.	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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 5178

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a rehabilitation specialist. or Must be treated by a plastic surgeon.	
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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 5360

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a plastic surgeon.	
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	Pathological hyperprolactinaemia	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Quinagolide	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	Compliance with Authority Required procedures - Streamlined Authority Code 5406

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a plastic surgeon. or Must be treated by a rehabilitation specialist.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 5452

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised panitumumab.	
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.	Compliance with Authority Required procedures - Streamlined Authority Code 5469

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 5472

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	
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	Compliance with Authority Required procedures - Streamlined Authority Code 5478

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 5500

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Scleroderma oesophagus	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Rabeprazole		
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Tyrosinaemia	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			docosahexanoic acid Amino acid formula with vitamins and minerals without phenylalanine and tyrosine Amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid Glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine Glycomacropeptide and essential amino acids with vitamins and minerals Phenylalanine with carbohydrate		
C5534	P5534	CN5534	Amino acid formula with fat, carbohydrate without methionine Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexanoic acid Amino acid formula with vitamins and minerals without methionine Amino acid formula with vitamins and minerals without methionine and supplemented with arachidonic acid and docosahexaenoic acid	Pyridoxine non-responsive homocystinuria	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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 without valine, leucine and isoleucine Amino acid formula with vitamins and minerals without valine, leucine and isoleucine Amino acid formula with vitamins and	Maple syrup urine disease	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid Amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid Isoleucine with carbohydrate Valine with carbohydrate		
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	
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 -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit; Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.	Code 5635
C5636	P5636	CN5636	Vancomycin	Antibiotic associated pseudomembranous colitis The condition must be due to Clostridium difficile; AND Patient must have an intolerance to metronidazole.	Compliance with Authority Required procedures
C5637	P5637	CN5637	Azithromycin	Trachoma	
C5638	P5638	CN5638	Clarithromycin	Bordetella pertussis	
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	Major depressive disorders	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Moclobemide Reboxetine Venlafaxine		
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	Compliance with Authority Required procedures - Streamlined Authority Code 5657

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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 -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	Compliance with Authority Required procedures -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be as monotherapy; AND The treatment must be limited to up to 6 months per episode.	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	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be associated with bipolar I disorder; AND The treatment must be limited to up to 6 months per episode.	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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	Code 5798
C5801	P5801	CN5801	Vancomycin	Endocarditis The treatment must be for prophylaxis; AND Patient must be hypersensitive to penicillin.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be limited to up to 6 months per episode.	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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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 -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	Compliance with

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 5953

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.	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	Phenylketonuria	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			acid		
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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be immunosuppressed.	Streamlined Authority Code 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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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 -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be undergoing palliative care.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Severe dry eye syndrome, including Sjogren's syndrome	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			glycol		
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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 -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					Streamlined Authority Code 6170
C6171	P6171	CN6171	Macrogol 3350	Constipation Patient must be receiving palliative care.	Compliance with Authority Required procedures - Streamlined Authority Code 6171
C6172	P6172	CN6172	Carbomer Carmellose Hypromellose 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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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;	Compliance with Authority Required procedures - Streamlined Authority Code 6193

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be up to the age of 24 months.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	Corticosteroid-responsive dermatoses	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Methylprednisolone Mometasone	The condition must cover 40-60% of the patient's body surface area.	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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Detrusor overactivity	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Propantheline		
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	Bone pain	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Indometacin Naproxen	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	Necrobiosis lipoidica	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Triamcinolone		
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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have 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.	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.	Compliance with Authority Required procedures - Streamlined Authority Code 6318

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The name of the specialist must be included in the authority application.	
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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	Compliance with

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Continuing Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.	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	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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Vildagliptin with metformin	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.	Code 6344
C6345	P6345	CN6345	Silver sulfadiazine	Stasis ulcers	
C6346	P6346	CN6346	Linagliptin Saxagliptin	Diabetes mellitus type 2 The treatment must be in combination with metformin; or	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Sitagliptin Vildagliptin	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.	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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	Compliance with Authority Required procedures - Streamlined Authority Code 6363

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				criterion before being eligible for PBS-subsidised treatment with this drug.	
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;	Compliance with Authority Required procedures - Streamlined Authority Code 6370

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	Compliance with Authority Required procedures - Streamlined Authority Code 6376

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 6383

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.	
C6387	P6387	CN6387	Naproxen	Bone pain The condition must be due to malignant disease.	
C6390	P6390	CN6390	Octreotide	Functional carcinoid tumour The condition must be causing intractable symptoms; AND Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents; AND Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate; AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Authority Required procedures - Streamlined Authority Code 6390
C6394	P6394	CN6394	Desferrioxamine	Disorders of erythropoiesis The condition must be associated with treatment-related chronic iron overload.	Compliance with Authority Required procedures - Streamlined Authority Code 6394
C6395	P6395	CN6395	Terbinafine	Onychomycosis The condition must be proximal or extensive (greater than 80% nail involvement); AND Patient must have failed to respond to topical treatment; AND The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider. or The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The date of the pathology report must be provided at the time of application and must not be more than 12 months old	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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,	Compliance with Authority Required procedures - Streamlined Authority Code 6443

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 6444

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 6464

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	Compliance with Authority Required procedures - Streamlined Authority Code 6524

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 6578

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	
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	Compliance with Authority Required procedures - Streamlined Authority Code 6604

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 6631

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not have renal impairment; AND Must be treated by a nephrologist.	
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;	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 6847

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have demonstrated compliance with, and an ability to tolerate this therapy; AND Must be treated by a neurologist.	
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;	Compliance with Authority Required procedures - Streamlined Authority Code 6871

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 6882

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 6886

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				cycle of cytotoxic chemotherapy.	
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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	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	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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;	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must be in combination with other antiretroviral agents.	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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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;	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				antispastic agents; AND Patient must have chronic spasticity due to spinal cord injury.	Code 7153
C7164	P7164	CN7164	Goserelin	Anticipated premature ovarian failure Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure; AND Patient must not receive more than 6 months' of treatment for this condition in a lifetime; Patient must be pre-menopausal.	
C7258	P7258	CN7258	Eribulin	Advanced (unresectable and/or metastatic) liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND The condition must be dedifferentiated, myxoid, round-cell or pleomorphic subtype; AND Patient must have received prior chemotherapy treatment including an anthracycline and ifosfamide (unless contraindicated) for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; Patient must be aged 18 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 7258
C7273	P7273	CN7273	Icatibant	Anticipated emergency treatment of an acute attack of hereditary angioedema Initial Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency; AND Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema; AND The condition must be assessed by a clinical immunologist. or The condition must be assessed by a respiratory physician. or The condition must be assessed by a specialist allergist. or The condition must be assessed by a general physician experienced in the	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				management of patients with hereditary angioedema. The name of the specialist consulted must be provided at the time of application for initial supply. The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.	
C7274	P7274	CN7274	Icatibant	Anticipated emergency treatment of an acute attack of hereditary angioedema Continuing Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
C7275	P7275	CN7275	Vitamins, minerals and trace elements formula	Dietary management of conditions requiring a highly restrictive therapeutic diet Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet; AND Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations; Patient must be aged 3 years or older.	
C7280	P7280	CN7280	Eribulin	Advanced (unresectable and/or metastatic) liposarcoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop progressive disease while being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; Patient must be aged 18 years or older.	Compliance with Authority Required procedures - Streamlined Authority Code 7280
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.	
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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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)	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 7505

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(SGLT2) inhibitor, metformin and a gliptin for this condition.	
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	Diabetes mellitus type 2 Initial treatment	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Sitagliptin with metformin	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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 7509

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 7524

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 7528

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 7532

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				pegvisomant. In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.	
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	Diabetes mellitus type 2 Continuing treatment	Compliance with Authority Required procedures -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Saxagliptin with dapagliflozin	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.	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	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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Pravastatin Rosuvastatin Simvastatin		
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	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have 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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 7645

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 7695

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	
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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 7876

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be associated with bipolar I disorder; AND The treatment must be as monotherapy.	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	Compliance with Authority Required procedures - Streamlined Authority Code 7944

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				less than a partial response or progression of disease within 6 months after completion of a prior rituximab-containing regimen.	
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.	Compliance with Authority Required procedures - Streamlined Authority Code 7957

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 7958

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 7966

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 7996

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 8161

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	
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-	Compliance with Authority Required procedures - Streamlined Authority Code 8183

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition.	
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	Compliance with Authority Required procedures -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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/1.73m^2; 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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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;	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 8606

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	
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.	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Rectified Authorised Version registered 09/08/2024 F2024C00520

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.	
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	Compliance with

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must not have experienced respiratory failure.	
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	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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Rabeprazole		
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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;	Compliance with Authority Required procedures - Streamlined Authority Code 8844

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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;	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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)	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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;	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
C8887	P8887	CN8887	Etanercept	Severe chronic plaque psoriasis Subsequent continuing treatment, whole body Patient must have previously received PBS-subsidised treatment with this	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				drug for this condition 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.	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);	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C8902	P8902	CN8902	Esomeprazole	Gastro-oesophageal reflux disease Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.	Compliance with Authority Required procedures
C8921	P8921	CN8921	Febuxostat	Chronic gout The condition must be either chronic gouty arthritis or chronic tophaceous gout; AND Patient must have a medical contraindication to allopurinol. or Patient must have a documented history of allopurinol hypersensitivity	Compliance with Authority Required procedures - Streamlined Authority Code 8921

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				syndrome. or Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.	
C8929	P8929	CN8929	Botulinum toxin type A purified neurotoxin complex Clostridium botulinum type A toxin - haemagglutinin complex	Moderate to severe spasticity of the upper limb Patient must have cerebral palsy; Patient must be aged 18 years or older; Must be treated by a neurologist. or Must be treated by an orthopaedic surgeon. or Must be treated by a paediatrician. or Must be treated by a rehabilitation specialist. or Must be treated by a plastic surgeon.	Compliance with Authority Required procedures - Streamlined Authority Code 8929
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.	Compliance with Authority Required procedures - Streamlined Authority Code 8940

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 8955

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 -	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
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.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				treatment failure.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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 mIU/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.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 mIU/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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 mIU/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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 9156

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.	
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.	Compliance with Authority Required procedures - Streamlined Authority Code 9188

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 9233

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 9252

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				mg every four weeks under a weight based or flat dosing regimen.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 9261

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required procedures - Streamlined Authority Code 9313

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				effective dose.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				cure or a substantial remission; AND Patient must 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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 9334

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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).	
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	Compliance with Written Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C9380	P9380	CN9380	Etanercept Tocilizumab	Severe active juvenile idiopathic arthritis Continuing Treatment - balance of supply	Compliance with Authority Required

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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)	Compliance with Written Authority

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 -	Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				PBS-subsidised biological medicine therapy in this treatment cycle.	
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.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.	
C9429	P9429	CN9429	Golimumab Ixekizumab Secukinumab	Ankylosing spondylitis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks 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	Ankylosing spondylitis	Compliance with

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Golimumab Ixekizumab Secukinumab Tofacitinib Upadacitinib	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.	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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The condition must be 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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application. The treatment must not exceed 0.8mg per m^2 for the first dose of a treatment cycle (Day 1), and 0.5mg per m^2 for subsequent doses (Days 8 and 15) within a treatment cycle. Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 9472

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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)	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 -	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				PBS-subsidised biological medicine therapy in this treatment cycle.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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).	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures -

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				disease.	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	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	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
			Clostridium botulinum type A toxin - haemagglutinin complex IncobotulinumtoxinA	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.	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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	Authority Required procedures - Streamlined Authority Code 9584

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	Compliance with Authority Required procedures - Streamlined Authority Code 9591

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 9593

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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 m^2 for all doses within a treatment cycle	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.	
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;	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				Patient must 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.	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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				relevant pathology report(s) need(s) to be provided	
C9622	P9622	CN9622	Rifabutin	Mycobacterium avium complex infection The treatment must be for prophylaxis; AND Patient must be human immunodeficiency virus (HIV) positive; AND Patient must have CD4 cell counts of less than 75 per cubic millimetre.	Compliance with Authority Required procedures - Streamlined Authority Code 9622
C9623	P9623	CN9623	Deferiprone	Iron overload Patient must have thalassaemia major; AND Patient must be unable to take desferrioxamine therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 9623
C9624	P9624	CN9624	Dornase alfa	Cystic fibrosis Patient must be 5 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily. To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment (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	Compliance with Authority Required procedures - Streamlined Authority Code 9624

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				agreement of benefit as there is always the possibility of harm from unnecessary use.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 9632

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 9668

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C9711	P9711	CN9711	Ustekinumab	Severe Crohn disease	Compliance with

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C9721	P9721	CN9721	Infliximab	Moderate to severe Crohn disease First continuing treatment Must be treated by a gastroenterologist (code 87); or	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures - Streamlined Authority Code 9732

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
C9754	P9754	CN9754	Infliximab	Moderate to severe ulcerative colitis Balance of supply	Compliance with Authority Required

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	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	Compliance with Authority Required procedures - Streamlined Authority Code 9762

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				The treatment must not be used in combination with any other non-calcium phosphate binding agents; AND Patient must be undergoing dialysis for chronic kidney disease.	
C9764	P9764	CN9764	Ciclosporin	Management of transplant rejection Management (initiation, stabilisation and review of therapy) Patient must have had an organ or tissue transplantation; AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Authority Required procedures - Streamlined Authority Code 9764
C9770	P9770	CN9770	Golimumab	Moderate to severe ulcerative colitis Continuing treatment Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; Patient must be aged 18 years or older. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request sufficient quantity for up to 24 weeks of treatment under this restriction. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with	Compliance with Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				(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.	
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.	Compliance with Authority Required procedures - Streamlined Authority Code 9775

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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 infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.	
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

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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.	Compliance with Written Authority Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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	Compliance with Written Authority Required procedures

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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)	Compliance with Written Authority

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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	Required procedures

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
				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.	
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 -

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
					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
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

Clause 1

Circumstances Code	Purposes Code	Conditions Code	Listed Drug	Circumstances and Purposes	Authority Requirements (part of Circumstances; or Conditions)
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