Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

March 2021

Cumulative for December 2020, January, February and March 2021

PHARMAC
TE PĀTAKA WHAIORANGA

Contents

Summary of decisions
EFFECTIVE 1 MARCH 2021

- Bromocriptine tab 2.5 mg – restriction added
- Clotrimazole (Clomazol) crm 1%, 20 g – price increase
- Clozapine (Versacloz) oral liq 50 mg per ml, 100 ml – new listing
- Cocaine hydrochloride (Biomed) soln 4%, 2 ml syringe – price increase
- Diltiazem hydrochloride (Dilzem) tab 60 mg – to be delisted 1 January 2022
- Dimethyl fumarate (Tecfidera) cap 120 mg and 240 mg – amended restriction criteria and addition of note
- Empagliflozin (Jardiance) tab 10 mg and tab 25 mg – amended restriction criteria
- Empagliflozin with metformin hydrochloride (Jardiamet) tab 5 mg with 500 mg and 1,000 mg metformin hydrochloride and tab 12.5 mg with 500 mg and 1,000 mg metformin hydrochloride – amended restriction criteria
- Fat-modified feed (e.g. Monogen) powder 12.8 g protein, 68.6 g carbohydrate and 12.9 g fat per 100 g, 400 g can – new listing
- Fat-modified feed (e.g. Monogen) powder 12.9 g protein, 69.1 g carbohydrate and 12.9 g fat per 100 g, 400 g can – to be delisted 1 December 2021
- Fingolimod (Gilenya) cap 0.5 mg – amended restriction criteria and addition of note
- Gadoteric acid (e.g. Clariscan) inj 279.30 mg per ml, 10 ml and 15 ml prefilled syringe and inj 279.30 mg per ml, 5 ml, 10 ml and 20 ml vial – new listing
- Glatiramer acetate (Copaxone) inj 40 mg prefilled syringe – amended restriction criteria and addition of note
- Glyceryl trinitrate (Nitrolingual Pump Spray) oral pump spray, 400 mcg per dose, 250 dose – price increase
- Glycopyrronium bromide (Max Health) inj 200 mcg per ml, 1 ml ampoule – price increase
- Influenza vaccine inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) (Afluria Quad Junior (2021 Formulation)), inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Afluria Quad (2021 Formulation)) and inj 60 mcg in 0.5 ml syringe (adjuvanted quadrivalent vaccine) (Fluad Quad (2021 Formulation)) – new listing
- Influenza vaccine inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) (Afluria Quad Junior (2020 Formulation)) and inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) (Afluria Quad (2020 Formulation) and (Influvac Tetra (2020 formulation)) – delisted 1 March 2021

Summary of decisions – effective 1 March 2021 (continued)

- Interferon beta-1-alpha inj 6 million iu in 0.5 ml pen injector (Avonex Pen) and inj 6 million iu in 0.5 ml syringe (Avonex) – amended restriction criteria and addition of note
- Interferon beta-1-beta inj 8 million iu per ml, 1 ml vial – amended restriction criteria and addition of note
- Ivacaftor (Kalydeco) tab 150 mg, oral granules 50 mg and 75 mg, sachet – new listing
- Low-calcium formula (e.g. Locasol) powder 14.6 g protein, 55.2 g carbohydrate and 25.8 g fat per 100 g, 400 g can – new listing
- Low-calcium formula (e.g. Locasol) powder 14.6 g protein, 53.7 g carbohydrate and 26.1 g fat per 100 g, 400 g can – to be delisted 1 September 2021
- Low-GI enteral feed 1 kcal/ml (Glucerna Select) liquid 5 g protein, 9.6 g carbohydrate and 5.4 g fat per 100 ml, 500 ml bottle – new listing
- Low-GI enteral feed 1 kcal/ml (Glucerna Select RTH (Vanilla)) liquid 5 g protein, 9.6 g carbohydrate and 5.4 g fat per 100 ml, 1,000 ml bottle – to be delisted 1 September 2021
- Low-GI oral feed 1 kcal/ml (Glucerna Select (Vanilla)) liquid 5 g protein, 9.6 g carbohydrate and 5.4 g fat per 100 ml, 250 ml bottle – to be delisted 1 September 2021
- Low-GI oral feed 1 kcal/ml (Resource Diabetic (Vanilla)) liquid 6 g protein, 9.5 g carbohydrate, 4.7 g fat and 2.6 g fibre per 100 ml, can – to be delisted 1 May 2021
- Multiple Sclerosis Treatments – amended restriction criteria
- Natalizumab (Tysabri) inj 20 mg per ml, 15 ml vial – amended restriction criteria and addition of note
- Nitrofurantoin (Macrobid) cap modified-release 100 mg – new listing and addition of HSS
- Ocrelizumab (Ocrevus) inj 30 mg per ml, 10 ml vial – amended restriction criteria and addition of note
- Olaparib (Lynparza) cap 50 mg – to be delisted 1 July 2021
- Omeprazole cap 10 mg (Omeprazole actavis 10), cap 20 mg (Omeprazole actavis 20) and cap 40 mg (Omeprazole actavis 40) – new Pharmacode listing and addition of HSS
- Omeprazole cap 10 mg (Omeprazole actavis 10), cap 20 mg (Omeprazole actavis 20) and cap 40 mg (Omeprazole actavis 40) – old Pharmacodes to be delisted 1 August 2021

Summary of decisions – effective 1 March 2021 (continued)

- Phenoxymethylpenicillin [penicillin V] (Cilicaine VK) cap 500 mg – new Pharmacode listing
- Rituximab (Riximyo) inj 10 mg per ml, 10 ml and 50 ml vial – amended restriction criteria
- Sodium alginate with sodium bicarbonate and calcium carbonate (Acidex) oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml – price increase
- Terbinafine (Deolate) tab 250 mg – new pack size listing and addition of HSS
- Teriflunomide (Aubagio) tab 14 mg – price decrease, addition of HSS, amended restriction criteria and addition of note
- Timolol maleate tab 10 mg – restriction added

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Section H changes to Part II

Effective 1 March 2021

ALIMENTARY TRACT AND METABOLISM

5 SODIUM ALGINATE WITH SODIUM BICARBONATE AND CALCIUM CARBONATE (↑ price)

Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml	5.24	500 ml	Acidex

7 GLYCOPYRRONIUM BROMIDE (↑ price)

Inj 200 mcg per ml, 1 ml ampoule	65.45	10	Max Health

8 OMEPRAZOLE (new Pharmacode listing and addition of HSS)

Cap 10 mg – **1% DV Aug-21 to 2023**	1.94	90	**Omeprazole actavis 10**
Cap 20 mg – **1% DV Aug-21 to 2023**	1.86	90	**Omeprazole actavis 20**
Cap 40 mg – **1% DV Aug-21 to 2023**	3.11	90	**Omeprazole actavis 40**

Note – these are new Pharmacode listings.

8 OMEPRAZOLE (delisting)

Cap 10 mg	1.98	90	Omeprazole actavis 10
Cap 20 mg	1.96	90	Omeprazole actavis 20
Cap 40 mg	3.12	90	Omeprazole actavis 40

Note – these delists apply to Pharmacodes 2524317, 2524325 and 2524333 from 1 August 2021.

10 EMPAGLIFLOZIN (amended restriction criteria)

➔Tab 10 mg	58.56	30	Jardiance
➔Tab 25 mg	58.56	30	Jardiance

Restricted
Initiation
Either:
1 For continuation use; or
2 All of the following:
- 2.1 Patient has type 2 diabetes; and
- 2.2 Any of the following:
  - 2.2.1 Patient is Maaori or any Pacific ethnicity*****; or
  - 2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent **(see note a)***; or
  - 2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*****; or
  - 2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*****; or
  - 2.2.5 Patient has diabetic kidney disease **(see note b)***; and
- 2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months; and
- 2.4 Treatment will not be used in combination with a funded GLP-1 agonist.

Note: ***Criteria intended to** ~~Criteria 2.1 – 2.5~~ describe patients at high risk of cardiovascular or renal complications of diabetes.

a) **Pre-existing cardiovascular disease or risk equivalent** ~~* D~~**d**efined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

b) **Diabetic kidney disease** ~~** D~~**d**efined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m^2 in the presence of diabetes, without alternative cause.

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 March 2021 (continued)

11 EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE (amended restriction criteria)

➔Tab 5 mg with 1,000 mg metformin hydrochloride	58.56	60	Jardiamet
➔Tab 5 mg with 500 mg metformin hydrochloride	58.56	60	Jardiamet
➔Tab 12.5 mg with 1,000 mg metformin hydrochloride	58.56	60	Jardiamet
➔Tab 12.5 mg with 500 mg metformin hydrochloride	58.56	60	Jardiamet

Restricted
Initiation
Either:
1 For continuation use; or
2 All of the following:
  2.1 Patient has type 2 diabetes; and
  2.2 Any of the following:
    2.2.1 Patient is Maaori or any Pacific ethnicity*****; or
    2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent **(see note a)***; or
    2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*****; or
    2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*****; or
    2.2.5 Patient has diabetic kidney disease **(see note b)***; and
  2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months; and
  2.4 Treatment will not be used in combination with a funded GLP-1 agonist.

Note: ***Criteria intended to** ~~Criteria 2.1 – 2.5~~ describe patients at high risk of cardiovascular or renal complications of diabetes.

a) **Pre-existing cardiovascular disease or risk equivalent** ~~*~~ **D**~~d~~efined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

b) **Diabetic kidney disease** ~~**~~ **D**~~d~~efined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m^2 in the presence of diabetes, without alternative cause.

CARDIOVASCULAR SYSTEM

42 TIMOLOL MALEATE – **Restricted: For continuation only** (restriction added)

➔Tab 10 mg			

43 DILTIAZEM HYDROCHLORIDE (delisting)

Tab 60 mg	8.50	100	Dilzem

Note – Dilzem tab 60 mg to be delisted from 1 January 2022.

47 GLYCERYL TRINITRATE (↑ price)

Oral pump spray, 400 mcg per dose	6.09	250 dose	Nitrolingual Pump Spray

DERMATOLOGICALS

53 CLOTRIMAZOLE (↑ price)

Crm 1%	0.77	20 g	Clomazol

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 March 2021 (continued)

INFECTIONS

77 PHENOXYMETHYLPENICILLIN [PENICILLIN V] (new Pharmacode listing)
Cap 500 mg – **1% DV Sep-18 to 2021** ..... 4.26 50 **Cilicaine VK**
Note – this is a new Pharmacode listing, 2602873. Pharmacode 2048868 to be delisted from 1 August 2021.

80 NITROFURANTOIN (new listing and addition of HSS)
Cap modified-release 100 mg – **1% DV Aug-21 to 2023** ..... 86.40 100 **Macrobid**

83 TERBINAFINE (new pack size listing and addition of HSS)
Tab 250 mg – **1% DV Aug-21 to 2023**..... 8.15 84 **Deolate**
Note – Deolate tab 250 mg, 14 tab to be delisted from 1 August 2021.

NERVOUS SYSTEM

105 BROMOCRIPTINE (restriction added)
Tab 2.5 mg – **Restricted: For continuation only**

108 COCAINE HYDROCHLORIDE (↑ price)
Soln 4%, 2 ml syringe..... 28.76 1 Biomed

119 CLOZAPINE (new listing)
Oral liq 50 mg per ml..... 67.62 100 ml Versacloz

122 Multiple Sclerosis Treatments (amended restriction – new criteria shown)

Restricted
Initiation - Multiple sclerosis
Neurologist or general physician
Re-assessment required after 12 months
All of the following

1 Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
2 Patients must have Clinically Definite Relapsing multiple sclerosis with or without underlying progression; and
3 Patients must have an EDSS score between 0 – 6.0 (inclusive); and
4 Patient has had at least 1 significant relapse of multiple sclerosis in the previous 12 months or 2 significant relapses in the past 24 months; and
5 All of the following:
5.1 Each significant relapse must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/ physician must be satisfied that the clinical features were characteristic); and
5.2 Each significant relapse is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
5.3 Each significant relapse has lasted at least one week and has started at least one month after the onset of a previous relapse; and
5.4 Each significant relapse can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C); and
5.5 Either
5.5.1 Each significant relapse is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or

continued...

Changes to Section H Part II – effective 1 March 2021 (continued)

continued...

5.5.2 Each significant relapse is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and

6 Evidence of new inflammatory activity on an MR scan within the past 24 months; and

7 Any of the following:

7.1 A sign of that new inflammatory activity is a gadolinium enhancing lesion; or

7.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or

7.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or

7.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse that occurred within the last 2 years; or

7.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MR scan.

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier. Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

Continuation - Multiple sclerosis
Neurologist or general physician
Patient has had an EDSS score of 0 to 6.0 (inclusive) at any time in the last six months (i.e. the patient has walked 100 metres or more with or without aids in the last six months).

122 DIMETHYL FUMARATE (amended restriction criteria and addition of note)

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

➔	Cap 120 mg	520.00	14	Tecfidera
➔	Cap 240 mg	2,000.00	56	Tecfidera

~~Restricted~~
~~Initiation~~
~~Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).~~

122 FINGOLIMOD (amended restriction criteria and addition of note)

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

➔	Cap 0.5 mg	2,200.00	28	Gilenya

~~Restricted~~
~~Initiation~~
~~Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).~~

123 NATALIZUMAB (amended restriction criteria and addition of note)

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

➔	Inj 20 mg per ml, 15 ml vial	1,750.00	1	Tysabri

~~Restricted~~
~~Initiation~~
~~Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).~~

Changes to Section H Part II – effective 1 March 2021 (continued)

123 OCRELIZUMAB (amended restriction criteria and addition of note)
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.
➔ Inj 30 mg per ml, 10 ml vial ..... 9,346.00 1 Ocrevus

~~Restricted~~
~~Initiation~~
~~Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).~~

123 TERIFLUNOMIDE (↓ price, addition of HSS, amended restriction criteria and addition of note)
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.
➔ Tab 14 mg – **1% DV Jun-21 to 2023** ..... 659.90 28 **Aubagio**

~~Restricted~~
~~Initiation~~
~~Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).~~

123 ~~Other Multiple Sclerosis Treatments~~

~~Restricted~~
~~Initiation~~
~~Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).~~

123 GLATIRAMER ACETATE (amended restriction criteria and addition of note)
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.
➔ Inj 40 mg prefilled syringe ..... 2,275.00 12 Copaxone

123 INTERFERON BETA-1-ALPHA (amended restriction criteria and addition of note)
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.
➔ Inj 6 million iu in 0.5 ml pen injector ..... 1,170.00 4 Avonex Pen
➔ Inj 6 million iu in 0.5 ml syringe ..... 1,170.00 4 Avonex

123 INTERFERON BETA-1-BETA (amended restriction criteria and addition of note)
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.
➔ Inj 8 million iu per ml, 1 ml vial

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

135 OLAPARIB (delisting)
➔ Cap 50 mg ..... 7,402.00 448 Lynparza
Note – Lynparza cap 50 mg to be delisted from 1 July 2021.

Changes to Section H Part II – effective 1 March 2021 (continued)

185 RITUXIMAB (RIXIMYO) (amended restriction criteria – only new criteria shown only)

➔ Inj 10 mg per ml, 10 ml vial	275.33	2	Riximyo
➔ Inj 10 mg per ml, 50 ml vial	688.20	1	Riximyo

Restricted

Initiation – Membranous nephropathy

Re-assessment required after 6 weeks

All of the following:

1 Either

1.1 Patient has biopsy-proven primary/idiopathic membranous nephropathy*; or

1.2 Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of >60ml/min/1.73m^2; and

2 Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note); and

3 The total rituximab dose would not exceed the equivalent of 375mg/m^2 of body surface area per week for a total of 4 weeks.

Continuation – Membranous nephropathy

Re-assessment required after 6 weeks

All of the following:

1 Patient was previously treated with rituximab for membranous nephropathy*; and

2 Either

2.1 Treatment with rituximab was previously successful, but the condition has relapsed, and the patient now requires repeat treatment; or

2.2 Patient achieved partial response to treatment and requires repeat treatment (see Note); and

3 The total rituximab dose used would not exceed the equivalent of 375 mg/ m^2 of body surface area per week for a total of 4 weeks.

Notes:

a) Indications marked with * are unapproved indications.

b) High risk of progression to end-stage kidney disease defined as >5g/day proteinuria.

c) Conservative measures include renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents unless contraindicated or the patient has experienced intolerable side effects.

d) Partial response defined as a reduction of proteinuria of at least 50% from baseline, and between 0.3 grams and 3.5 grams per 24 hours.

RESPIRATORY SYSTEM AND ALLERGIES

212 IVACAFTOR (new listing)

➔ Tab 150 mg	29,386.00	56	Kalydeco
➔ Oral granules 50 mg, sachet	29,386.00	56	Kalydeco
➔ Oral granules 75 mg, sachet	29,386.00	56	Kalydeco

Restricted

Initiation

Respiratory specialist or paediatrician

All of the following:

1 Patient has been diagnosed with cystic fibrosis; and

2 Either:

2.1 Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; or

2.2 Patient must have other gating (class III) mutation (G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N and S549R) in the CFTR gene on at least 1 allele; and

continued...

Changes to Section H Part II – effective 1 March 2021 (continued)

continued...

3 Patients must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
4 Treatment with ivacaftor must be given concomitantly with standard therapy for this condition; and
5 Patient must not have an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing treatment with ivacaftor; and
6 The dose of ivacaftor will not exceed one tablet or one sachet twice daily; and
7 Applicant has experience and expertise in the management of cystic fibrosis.

VARIOUS

225 GADOTERIC ACID (new listing)

Inj 279.30 mg per ml, 10 ml prefilled syringe			*e.g. Clariscan*
Inj 279.30 mg per ml, 15 ml prefilled syringe			*e.g. Clariscan*
Inj 279.30 mg per ml, 5 ml vial			*e.g. Clariscan*
Inj 279.30 mg per ml, 10 ml vial			*e.g. Clariscan*
Inj 279.30 mg per ml, 20 ml vial			*e.g. Clariscan*

SPECIAL FOODS

238 LOW-GI ENTERAL FEED 1 KCAL/ML (new listing)

➔ Liquid 5 g protein, 9.6 g carbohydrate and 5.4 g fat per 100 ml, 500 ml bottle	3.75	500 ml	Glucerna Select

238 LOW-GI ENTERAL FEED 1 KCAL/ML (delisting)

➔ Liquid 5 g protein, 9.6 g carbohydrate and 5.4 g fat per 100 ml, 1,000 ml bottle	7.50	1,000 ml	Glucerna Select RTH (Vanilla)

Note – Glucerna Select RTH (Vanilla) liquid 5 g protein, 9.6 g carbohydrate and 5.4 g fat per 100 ml, 1,000 ml bottle to be delisted from 1 September 2021.

238 LOW-GI ORAL FEED 1 KCAL/ML (delisting)

➔ Liquid 5 g protein, 9.6 g carbohydrate and 5.4 g fat per 100 ml, 250 ml bottle	1.88	250 ml	Glucerna Select (Vanilla)

Note – Glucerna Select (Vanilla) liquid 5 g protein, 9.6 g carbohydrate and 5.4 g fat per 100 ml, 250 ml bottle to be delisted 1 September 2021.

238 LOW-GI ORAL FEED 1 KCAL/ML (delisting)

➔ Liquid 6 g protein, 9.5 g carbohydrate, 4.7 g fat and 2.6 g fibre per 100 ml, can	2.10	237 ml	Resource Diabetic (Vanilla)

Note – Resource Diabetic (Vanilla) liquid 6 g protein, 9.5 g carbohydrate, 4.7 g fat and 2.6 g fibre per 100 ml, can to be delisted from 1 May 2021

239 FAT-MODIFIED FEED (new listing)

➔ Powder 12.8 g protein, 68.6 g carbohydrate and 12.9 g fat per 100 g, 400 g can			*e.g. Monogen*

Changes to Section H Part II – effective 1 March 2021 (continued)

239 FAT-MODIFIED FEED (delisting)
➔ Powder 12.9 g protein, 69.1 g carbohydrate and 12.9 g fat per 100 g, 400 g can *e.g. Monogen*
Note – Monogen powder 12.9 g protein, 69.1 g carbohydrate and 12.9 g fat per 100 g, 400 g can to be delisted from 1 December 2021.

243 LOW-CALCIUM FORMULA (new listing)
Powder 14.6 g protein, 55.2 g carbohydrate and 25.8 g fat per 100 g, 400 g can *e.g. Locasol*

243 LOW-CALCIUM FORMULA (delisting)
Powder 14.6 g protein, 53.7 g carbohydrate and 26.1 g fat per 100 g, 400 g can *e.g. Locasol*
Note – Locasol powder 14.6 g protein, 53.7 g carbohydrate and 26.1 g fat per 100 g, 400 g can to be delisted from 1 September 2021.

VACCINES

254	INFLUENZA VACCINE (new listing)			
	➔ Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)	9.00	1	Afluria Quad Junior (2021 Formulation)
	➔ Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)	90.00	10	Afluria Quad (2021 Formualtion)
254	INFLUENZA VACCINE (new listing)			
	➔ Inj 60 mcg in 0.5 ml syringe (adjuvanted quadrivalent vaccine)	90.00	10	Fluad Quad (2021 Formulation)
	Restricted Initiation – People over 65 The patient is 65 years of age or over.			
254	INFLUENZA VACCINE (delisted)			
	➔ Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)	9.00	1	Afluria Quad Junior (2020 Formulation)
	➔ Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)	90.00	10	Afluria Quad (2020 Formualtion)
		9.00	1	Influvac Tetra (2020 formulation)

Note – Afluria Quad Junior (2020 Formulation) inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) and Afluria Quad (2020 Formualtion) and Influvac Tetra (2020 formulation) inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) delisted from 1 March 2021.

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 February 2021

ALIMENTARY TRACT AND METABOLISM

10 ~~Oral Hypoglycaemic Agents~~ (amended therapeutic name)
Blood Glucose Lowering Agents

10 EMPAGLIFLOZIN (new listing)

➔Tab 10 mg	58.56	30	Jardiance
➔Tab 25 mg	58.56	30	Jardiance

Restricted
Initiation
Either:
1 For continuation use; or
2 All of the following;
  2.1 Patient has type 2 diabetes; and
  2.2 Any of the following:
    2.2.1 Patient is Māori or any Pacific ethnicity; or
    2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent*; or
    2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or
    2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult; or
    2.2.5 Patient has diabetic kidney disease**; and
  2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months; and
  2.4 Treatment will not be used in combination with a funded GLP-1 agonist

Note: Criteria 2.2.1 – 2.2.5 describe patients at high risk of cardiovascular or renal complications of diabetes
* Defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
** Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m^2 in the presence of diabetes, without alternative cause.

10 EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE (new listing)

➔Tab 5 mg with 500 mg metformin hydrochloride	58.56	60	Jardiamet
➔Tab 5 mg with 1,000 mg metformin hydrochloride	58.56	60	Jardiamet
➔Tab 12.5 mg with 500 mg metformin hydrochloride	58.56	60	Jardiamet
➔Tab 12.5 mg with 1,000 mg metformin hydrochloride	58.56	60	Jardiamet

Restricted
Initiation
Either:
1 For continuation use; or
2 All of the following;
  2.1 Patient has type 2 diabetes; and
  2.2 Any of the following:
    2.2.1 Patient is Māori or any Pacific ethnicity; or
    2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent*; or
    2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or

continued...

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 February 2021 (continued)

continued...

2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult; or

2.2.5 Patient has diabetic kidney disease**; and

2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months; and

2.4 Treatment will not be used in combination with a funded GLP-1 agonist

Note: Criteria 2.2.1 – 2.2.5 describe patients at high risk of cardiovascular or renal complications of diabetes

* Defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

** Defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m^2 in the presence of diabetes, without alternative cause.

11	VILDAGLIPTIN (↓ price)			
	Tab 50 mg	35.00	60	Galvus
11	VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE (↓ price)			
	Tab 50 mg with 1,000 mg metformin hydrochloride	35.00	60	Galvumet
	Tab 50 mg with 850 mg metformin hydrochloride	35.00	60	Galvumet
13	ALGLUCOSIDASE ALFA (amended restriction criteria – affected criteria shown only)			
	➔Inj 50 mg vial	1,142.60	1	Myozyme

Continuation

Metabolic physician

Re-assessment required after 12 months

All of the following:

1 The treatment remains appropriate for the patient and the patient is benefiting from treatment; and
2 Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks; and
3 Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate premedication and/or adjustment of infusion rates; and
4 Patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by ERT; and
5 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
6 There is no evidence of life threatening progression of respiratory disease as evidenced by the needed for >14 days of invasive ventilation; and
7 There is no evidence of new or progressive cardiomyopathy.

14	ARGININE (new listing)			
	Inj 500 mg per ml, 10 ml vial			
14	BETAINE (amended restriction criteria – affected criteria shown only)			
	➔Powder for oral soln	575.00	180 g	Cystadane

Continuation

Metabolic physician

Re-assessment required after 12 months

The treatment remains appropriate and the patient is benefiting from treatment.

Changes to Section H Part II – effective 1 February 2021 (continued)

15 GALSULFASE (amended restriction criteria – affected criteria shown only)
➔Inj 1 mg per ml, 5 ml vial ..... 2,234.00 1 Naglazyme

Continuation
Metabolic physician
Re-assessment required after 12 months
All of the following:
1 The treatment remains appropriate for the patient and the patient is benefiting from treatment; and
2 Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate premedication and/or adjustment of infusion rates; and
3 Patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by Enzyme Replacement Therapy (ERT); and
4 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT.

16 SAPROPTERIN DIHYDROCHLORIDE (amended restriction criteria – affected criteria shown only)
➔Tab soluble 100 mg..... 1,452.70 30 Kuvan

Continuation
Metabolic physician
Re-assessment required after 12 months
All of the following:
1 Either:
  1.1 Following the initial one-month approval, the patient has demonstrated an adequate response to a 2 to 4 week trial of sapropterin with a clinically appropriate reduction in phenylalanine levels to support management of PKU during pregnancy; or
  1.2 On subsequent renewal applications, the patient has previously demonstrated response to treatment with sapropterin and maintained adequate phenylalanine levels to support management of PKU during pregnancy; and
2 Any of the following:
  2.1 Patient continues to be pregnant and treatment with sapropterin will not continue after delivery; or
  2.2 Patient is actively planning a pregnancy and this is the first renewal for treatment with sapropterin; or
  2.3 Treatment with sapropterin is required for a second or subsequent pregnancy to support management of their PKU during pregnancy; and
3 Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg; and
4 Sapropterin to be used alone or in combination with PKU dietary management; and
5 Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery.

17 SODIUM PHENYLBUTYRATE (amended restriction criteria – affected criteria shown only)
➔Grans 483 mg per g..... 2,106.00 174 g Pheburane

Continuation
Metabolic physician
Re-assessment required after 12 months
The treatment remains appropriate and the patient is benefiting from treatment.

19 MAGNESIUM SULPHATE (new listing and addition of HSS)
Inj 2 mmol per ml, 5 ml ampoule – **1% DV Jul-21 to 2023**..... 25.53 10 **Martindale**

19 MAGNESIUM SULPHATE (↑ price and delisting)
Inj 2 mmol per ml, 5 ml ampoule..... 28.00 10 DBL
Note – DBL inj 2 mmol per ml, 5 ml ampoule to be delisted from 1 July 2021.

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 February 2021 (continued)

BLOOD AND BLOOD FORMING ORGANS

31	HEPARIN SODIUM (↑ price)			
	Inj 1,000 iu per ml, 1 ml ampoule	245.26	50	Hospira
	Inj 5,000 iu per ml, 1 ml ampoule	70.33	5	Hospira
36	WATER (↑ price)			
	Inj 10 ml ampoule	7.19	50	Pfizer

CARDIOVASCULAR SYSTEM

42	METOPROLOL TARTRATE (↓ price)			
	Inj 1 mg per ml, 5 ml vial – **1% DV Feb-19 to 31 Jan 2022**	26.50	5	**Metoprolol IV Mylan**
43	DILTIAZEM HYDROCHLORIDE (delisting)			
	Tab 30 mg	4.60	100	Dilzem
	Note – Dilzem tab 30 mg to be delisted from 1 June 2021.			
50	SILDENAFIL (amended restriction criteria – affected criteria shown only)			
	➔ Tab 25 mg – **1% DV Sep-18 to 2021**	0.64	4	**Vedafil**
	➔ Tab 50 mg – **1% DV Sep-18 to 2021**	0.64	4	**Vedafil**
	➔ Tab 100 mg – **1% DV Sep-18 to 2021**	6.60	12	**Vedafil**
	➔ Inj 0.8 mg per ml, 12.5 ml vial			

Restricted
Initiation – tablets Pulmonary arterial hypertension
Any of the following:
1 All of the following:
- 1.1 Patient has pulmonary arterial hypertension (PAH); and
- 1.2 Any of the following:
  - 1.2.1 PAH is in Group 1 of the WHO (Venice) clinical classifications; or
  - 1.2.2 PAH is in Group 4 of the WHO (Venice) clinical classifications; or
  - 1.2.3 PAH is in Group 5 of the WHO (Venice) clinical classifications; and
- 1.3 Any of the following:
  - 1.3.1 PAH is in NYHA/WHO functional class II; or
  - 1.3.2 PAH is in NYHA/WHO functional class III; or
  - 1.3.3 PAH is in NYHA/WHO functional class IV; and
- 1.4 Either:
  - 1.4.1 All of the following:
    - 1.4.1.1 Patient has a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 1.4.1.2 Either:
      - 1.4.1.2.1 Patient has a mean pulmonary artery pressure (PAPm) > 25 mmHg; or
      - 1.4.1.2.2 Patient is peri Fontan repair; and
    - 1.4.1.3 Patient has a pulmonary vascular resistance (PVR) of at least 3 Wood Units or at least 240 International Units (dyn s cm-5); or
  - 1.4.2 Testing for PCWP, PAPm, or PVR cannot be performed due to the patient's young age ~~or health system capacity constraints~~; or

2 For use in neonatal units for persistent pulmonary hypertension of the newborn (PPHN); or
3 In-hospital stabilisation in emergency situations.

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 February 2021 (continued)

GENITO-URINARY SYSTEM

60	ERGOMETRINE MALEATE (↑ price)			
	Inj 500 mcg per ml, 1 ml ampoule	160.00	5	DBL Ergometrine

HORMONE PREPARATIONS

63	TESTOSTERONE CIPIONATE (↑ price)			
	Inj 100 mg per ml, 10 ml vial	85.00	1	Depo-Testosterone
66	MEDROXYPROGESTERONE ACETATE (↑ price)			
	Tab 2.5 mg	4.69	30	Provera
	Tab 5 mg	17.50	100	Provera
	Tab 10 mg	8.94	30	Provera
66	MEDROXYPROGESTERONE (↑ price)			
	Tab 100 mg	116.15	100	Provera HD

INFECTIONS

77	AMOXICILLIN (↑ price)			
	Inj 250 mg vial	15.97	10	Ibiamox
	Inj 500 mg vial	17.43	10	Ibiamox
	Inj 1 g vial	21.64	10	Ibiamox
77	AMOXICILLIN WITH CLAVULANIC ACID (new listing and addition of HSS)			
	Tab 500 mg with clavulanic acid 125 mg			
	– **1% DV Jul-21 to 2023**	0.89	10	**Curam Duo 500/125**
77	AMOXICILLIN WITH CLAVULANIC ACID (↑ price and delisting)			
	Tab 500 mg with clavulanic acid 125 mg	5.00	20	Augmentin
	Note – Augmentin tab 500 mg with clavulanic acid to be delisted from 1 July 2021.			
77	FLUCLOXACILLIN (↑ price)			
	Inj 250 mg vial	17.56	10	Flucloxin
	Inj 500 mg vial	18.78	10	Flucloxin
86	QUININE SULPHATE (delisting)			
	Tab 300 mg	61.91	500	Q300
	Note – Q300 tab 300 mg to be delisted 1 July 2021.			
90	VALGANCICLOVIR (amended restriction criteria – affected criteria shown only)			
	➔ Tab 450 mg – **1% DV May-19 to 2021**	225.00	60	**Valganciclovir Mylan**

Restricted
Initiation — Lung transplant cytomegalovirus prophylaxis
Relevant specialist
*Limited to 6 **12** months treatment*
~~Both~~ **All of the following**:
1 Patient has undergone a lung transplant; and
2 Either:
2.1 The donor was cytomegalovirus positive and the patient is cytomegalovirus negative; or

continued...

Changes to Section H Part II – effective 1 February 2021 (continued)

continued...

2.2 The recipient is cytomegalovirus positive; **and**

3 Patient has a high risk of CMV disease.

Initiation — transplant cytomegalovirus prophylaxis
Re-assessment required after ~~*Limited to 3 months treatment*~~
Patient has undergone a solid organ transplant and requires valganciclovir for CMV prophylaxis.

Continuation– transplant cytomegalovirus prophylaxis
Re-assessment required after 3 months
Either:

1 Both:
- **1.1 Patient has undergone a solid organ transplant and received anti-thymocyte globulin and requires valganciclovir therapy for CMV prophylaxis; and**
- **1.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following anti-thymocyte globulin; or**

2 Both:
- **2.1 Patient has received pulse methylprednisolone for acute rejection and requires further valganciclovir therapy for CMV prophylaxis; and**
- **2.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following pulse methylprednisolone.**

91 EMTRICITABINE WITH TENOFOVIR DISOPROXIL (amended restriction criteria – affected criteria shown only)
➔Tab 200 mg with tenofovir disoproxil 245 mg
(300.6 mg as a succinate) – **1% DV Jun-19 to 2022**.....61.15 30 **Teva**

Initiation – Pre-exposure prophylaxis
Re-assessment required after 3 months
All of the following:

1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and
2 Patient has undergone testing for HIV, syphilis and Hep B if not immune **and a full STI screen** in the previous two weeks; and
3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 3 months and is not contraindicated for treatment; and
4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce those risks; and
5 Patient has tested HIV negative and is not at risk of HIV seroconversion; and
6 Either:
- 6.1 All of the following:
  - 6.1.1 Patient is male or transgender; and
  - 6.1.2 Patient has sex with men; and
  - 6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and
  - 6.1.4 Any of the following:
    - 6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
    - 6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or
    - 6.1.4.3 Patient has used methamphetamine in the last three months; or
- 6.2 All of the following:
  - 6.2.1 Patient has a regular partner who has HIV infection; and
  - 6.2.2 Partner is either not on treatment or has a detectable viral load; and
  - 6.2.3 Condoms have not been consistently used.

continued...

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 February 2021 (continued)

continued...

Continuation – Pre-exposure prophylaxis
Re-assessment required after 3 months
All of the following:

1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and
2 Patient has undergone testing for HIV, syphilis and Hep B if not immune **and a full STI screen** in the previous two weeks; and
3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 12 months and is not contraindicated for treatment; and
4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce those risks; and
5 Patient has tested HIV negative and is not at risk of HIV seroconversion; and
6 Either:
  6.1 All of the following:
    6.1.1 Patient is male or transgender; and
    6.1.2 Patient has sex with men; and
    6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and
    6.1.4 Any of the following:
      6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
      6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or
      6.1.4.3 Patient has used methamphetamine in the last three months; or
  6.2 All of the following:
    6.2.1 Patient has a regular partner who has HIV infection; and
    6.2.2 Partner is either not on treatment or has a detectable viral load; and
    6.2.3 Condoms have not been consistently used.

97	PAMIDRONATE DISODIUM (↑ price)			
	Inj 3 mg per ml, 10 ml vial	27.53	1	Pamisol
	Inj 6 mg per ml, 10 ml vial	74.67	1	Pamisol

MUSCULOSKELETAL SYSTEM

101	FEBUXOSTAT (amended restriction criteria – new criteria shown only)			
	➔ Tab 80 mg	39.50	28	Adenuric
	➔ Tab 120 mg	39.50	28	Adenuric

Restricted
Initiation - Tumour lysis syndrome
Haematologist or oncologist
Reassessment required after 6 weeks
Both:
1 Patient is scheduled to receive cancer therapy carrying an intermediate or high risk of tumour lysis syndrome; and
2 Patient has a documented history of allopurinol intolerance.

Continuation - Tumour lysis syndrome
Haematologist or oncologist
Reassessment required after 6 weeks
The treatment remains appropriate and patient is benefitting from treatment.

➔ Restriction
(Brand) indicates a brand example only. It is not a contracted product.

Changes to Section H Part II – effective 1 February 2021 (continued)

103 IBUPROFEN (↑ price and addition of HSS)
Tab 200 mg – **1% DV Feb-21 to 2024** ..... 21.40 1,000 **Relieve**

NERVOUS SYSTEM

105 BENZATROPINE MESYLATE (↑ price)
Tab 2 mg ..... 9.59 60 Benztrop

109 LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE WITH CHLORHEXIDINE (↑ price)
Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringe ..... 103.32 10 Pfizer

111 MORPHINE SULPHATE (↑ price)
Inj 5 mg per ml, 1 ml ampoule ..... 6.99 5 DBL Morphine Sulphate
Inj 10 mg per ml, 1 ml ampoule ..... 5.61 5 DBL Morphine Sulphate
Inj 15 mg per ml, 1 ml ampoule ..... 7.08 5 DBL Morphine Sulphate
Inj 30 mg per ml, 1 ml ampoule ..... 7.28 5 DBL Morphine Sulphate

112 PETHIDINE HYDROCHLORIDE (↑ price)
Inj 50 mg per ml, 1 ml ampoule ..... 29.88 5 DBL Pethidine Hydrochloride
Inj 50 mg per ml, 2 ml ampoule ..... 30.72 5 DBL Pethidine Hydrochloride

115 VIGABATRIN (amended restriction criteria)
➔ Tab 500 mg

Restricted
Initiation
Re-assessment required after 15 months
Both:
1 Either:
1.1 Patient has infantile spasms; or
1.2 Both:
1.2.1 Patient has epilepsy; and
1.2.2 Either:
1.2.2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
1.2.2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; and
2 Either:
2.1 Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or
2.2 It is impractical or impossible (due to comorbid conditions~~, or health system capacity constraints~~) to monitor the patient's visual fields.

Notes: "Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance. Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

continued...

Changes to Section H Part II – effective 1 February 2021 (continued)

continued...

Continuation
Both:
1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and
2 Either:
  2.1 Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin; or
  2.2 It is impractical or impossible (due to comorbid conditions~~, or health system capacity constraints~~) to monitor the patient's visual fields.

Notes: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective. Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages

124 PHENOBARBITONE (new listing)
Inj 130 mg per ml, 1 ml vial

125 MODAFINIL (amended restriction criteria – affected criteria shown only)

➔Tab 100 mg	64.00	60	Modavigil

Restricted
Initiation – Narcolepsy
Neurologist or respiratory specialist
Re-assessment required after 24 months
All of the following:
1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
2 **Either** ~~Any of the following~~:
  2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
  ~~2.2 A multiple sleep latency test is not possible due to COVID-19 constraints on the health sector; or~~
  2.2 ~~2.3~~ The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and
3 Either:
  3.1 An effective dose of a listed formulation of methylphenidate or dexamphetamine has been trialled and discontinued because of intolerable side effects; or
  3.2 Methylphenidate and dexamphetamine are contraindicated.

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

139 ERLOTINIB (amended restriction criteria – affected criteria shown only)

➔Tab 100 mg	764.00	30	Tarceva
➔Tab 150 mg	1,146.00	30	Tarceva

~~Continuation – pandemic circumstances~~
~~*Re-assessment required after 6 months*~~
~~All of the following:~~
~~1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and~~
~~2 Erlotinib to be discontinued at progression; and~~
~~3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.~~

Changes to Section H Part II – effective 1 February 2021 (continued)

140 GEFITINIB (amended restriction criteria – affected criteria shown only)
➔ Tab 250 mg ..... 1,700.00 | 30 | Iressa

~~Continuation – pandemic circumstances~~
~~Re-assessment required after 6 months~~
~~All of the following:~~
~~1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and~~
~~2 Gefitinib to be discontinued at progression; and~~
~~3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.~~

144 SUNITINIB (amended restriction criteria – affected criteria shown only)
➔ Cap 12.5 mg ..... 2,315.38 | 28 | Sutent
➔ Cap 25 mg ..... 4,630.77 | 28 | Sutent
➔ Cap 50 mg ..... 9,261.54 | 28 | Sutent

~~Continuation – GIST pandemic circumstances~~
~~Re-assessment required after 6 months~~
~~All of the following:~~
~~1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and~~
~~2 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and~~
~~3 Sunitinib is to be discontinued at progression; and~~
~~4 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.~~

145 DOCETAXEL (↑ price)
Inj 10 mg per ml, 8 ml vial ..... 46.89 | 1 | DBL Docetaxel

146 ABIRATERONE ACETATE (amended restriction criteria – affected criteria shown only)
➔ Tab 250 mg ..... 4,276.19 | 120 | Zytiga

Continuation
Medical oncologist, radiation oncologist or urologist
Re-assessment required after 6 months
All of the following:
1 Significant decrease in serum PSA from baseline; and
~~1~~ **2** No evidence of clinical disease progression; and
~~2~~ **3** No initiation of taxane chemotherapy with abiraterone; and
~~3~~ **4** The treatment remains appropriate and the patient is benefiting from treatment.

148 OCTREOTIDE (↑ price)
Inj 50 mcg per ml, 1 ml ampoule ..... 56.87 | 5 | DBL Octreotide
Inj 100 mcg per ml, 1 ml ampoule ..... 40.00 | 5 | DBL Octreotide
Inj 500 mcg per ml, 1 ml ampoule ..... 145.00 | 5 | DBL Octreotide

148 OCTREOTIDE (amended restriction criteria – affected criteria shown only)
➔ Inj 10 mg vial ..... 1,772.50 | 1 | Sandostatin LAR
➔ Inj 20 mg vial ..... 2,358.75 | 1 | Sandostatin LAR
➔ Inj 30 mg vial ..... 2,951.25 | 1 | Sandostatin LAR

~~Restricted~~
~~Continuation – Acromegaly - pandemic circumstances~~
~~Re-assessment required after 6 months~~
~~All of the following:~~
~~1 Patient has acromegaly; and~~
~~2 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and~~
~~3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.~~

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 February 2021 (continued)

150 ETANERCEPT (new listing)
➔Inj 25 mg autoinjector – **5% DV Sep-19 to 2024** ..... 690.00 4 **Enbrel**

201 NIVOLUMAB (amended restriction criteria – affected criteria shown only)
➔Inj 10 mg per ml, 4 ml vial ..... 1,051.98 1 Opdivo
➔Inj 10 mg per ml, 10 ml vial ..... 2,629.96 1 Opdivo

Continuation
Medical oncologist
Re-assessment required after 4 months
Either:
1 All of the following:
1.1 Any of the following:
1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
1.2 Either:
1.2.1 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; or
1.2.2 Both:
1.2.2.1 Patient has measurable disease as defined by RECIST version 1.1; and
1.2.**2.2** Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and
1.3 No evidence of progressive disease according to RECIST criteria (see Note); and
1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
2 All of the following:
2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
2.2 Patient has signs of disease progression; and
2.3 Disease has not progressed during previous treatment with nivolumab.

202 PEMBROLIZUMAB (amended restriction criteria – affected criteria shown only)
➔Inj 25 mg per ml, 4 ml vial ..... 4,680.00 1 Keytruda

Continuation
Medical oncologist
Re-assessment required after 4 months
Either:
1 All of the following:
1.1 Any of the following:
1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
1.2 Either:
1.2.1 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; or
1.2.2 Both:
1.2.2.1 Patient has measurable disease as defined by RECIST version 1.1; and
1.2.**2.2** Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and

continued...

Changes to Section H Part II – effective 1 February 2021 (continued)

continued...

1.3 No evidence of progressive disease according to RECIST criteria (see Note); and
1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
2 All of the following:
2.1 Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
2.2 Patient has signs of disease progression; and
2.3 Disease has not progressed during previous treatment with pembrolizumab.

204 EVEROLIMUS (amended restriction criteria – affected criteria shown only)

➔ Tab 5 mg	4,555.76	30	Afinitor
➔ Tab 10 mg	6,512.29	30	Afinitor

~~Continuation – pandemic circumstances~~
~~*Re-assessment required after 6 months*~~
~~All of the following:~~
~~1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and~~
~~2 Everolimus to be discontinued at progression of SEGAs; and~~
~~3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.~~
~~Note: MRI should be performed at minimum once every 12 months, more frequent scanning should be performed with new onset of symptoms such as headaches, visual complaints, nausea or vomiting, or increase in seizure activity.~~

205 SIROLIMUS (amended restriction criteria – new criteria shown only)

➔ Tab 1 mg	749.99	100	Rapamune
➔ Tab 2 mg	1,499.99	100	Rapamune
➔ Oral liq 1 mg per ml	449.99	60 ml	Rapamune

Restricted
Initiation - severe non-malignant lymphovascular malformations*
Re-assessment required after 6 months
All of the following:
1 Patient has severe non-malignant lymphovascular malformation*; and
2 Any of the following:
2.1 Malformations are not adequately controlled by sclerotherapy and surgery; or
2.2 Malformations are widespread/extensive and sclerotherapy and surgery are not considered clinically appropriate; or
2.3 Sirolimus is to be used to reduce malformation prior to consideration of surgery; and
3 Patient is being treated by a specialist lymphovascular malformation multi-disciplinary team; and
4 Patient has measurable disease as defined by RECIST version 1.1 (see Note).

Continuation – severe non-malignant lymphovascular malformations*
Re-assessment required after 12 months
All of the following:
1 Either:
1.1 Patient's disease has had either a complete response or a partial response to treatment, or patient has stable disease according to RECIST version 1.1 (see Note); or
1.2 Patient's disease has stabilised or responded clinically and disease response to treatment has been clearly documents in patient notes; and
2 No evidence of progressive disease; and
3 The treatment remains clinically appropriate and the patient is benefitting from the treatment.
Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer et al. Eur J Cancer 2009;45:228-47)
Note: Indications marked with * are unapproved indications

continued...

Changes to Section H Part II – effective 1 February 2021 (continued)

continued...

Initiation - renal angiomyolipoma associated with tuberous sclerosis complex*
Nephrologist or Urologist
Re-assessment required after 6 months
Both:
1 Patient has tuberous sclerosis complex*; and
2 Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth.

Continuation - renal angiomyolipoma associated with tuberous sclerosis complex*
Re-assessment required after 12 months
All of the following:
1 Documented evidence of renal angiomyolipoma reduction or stability by magnetic resonance imaging (MRI) or ultrasound; and
2 Demonstrated stabilisation or improvement in renal function; and
3 The patient has not experienced angiomyolipoma haemorrhage or significant adverse effects to sirolimus treatment; and
4 The treatment remains appropriate and the patient is benefitting from treatment.
Note: Indications marked with * are unapproved indications

Initiation - refractory seizures associated with tuberous sclerosis complex*
Neurologist
Re-assessment required after 6 months
All of the following:
1 Patient has epilepsy with a background of documented tuberous sclerosis complex*; and
2 Either:
2.1 Both:
2.1.1 Vigabatrin has been trialled and has not adequately controlled seizures; and
2.1.2 Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least two of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note); or
2.2 Both:
2.2.1 Vigabatrin is contraindicated; and
2.2.2 Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least three of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note); and
3 Seizures have a significant impact on quality of life; and
4 Patient has been assessed and surgery is considered inappropriate for this patient, or the patient has been assessed and would benefit from mTOR inhibitor treatment prior to surgery.
Note: "Optimal treatment" is defined as treatment, which is indicated and clinically appropriate for the patient, given in adequate doses for the patients age, weight and other features affecting the pharmacokinetics of the drug, with good evidence of adherence. Women of childbearing age are not required to have a trial of sodium valproate.

Continuation - refractory seizures associated with tuberous sclerosis complex*
Neurologist
Re-assessment required after 12 months
Demonstrated significant and sustained improvement in seizure rate (e.g. 50% reduction in seizure frequency) or severity and/or patient quality of life compared with baseline prior to starting treatment sirolimus.
Note: Indications marked with * are unapproved indications

Changes to Section H Part II – effective 1 February 2021 (continued)

RESPIRATORY SYSTEM AND ALLERGIES

207 CETIRIZINE HYDROCHLORIDE (↑ price)

Oral liq 1 mg per ml	3.37	200 ml	Histaclear

208 NINTEDANIB (amended restriction criteria)

➔ Cap 100 mg	2,554.00	60	Ofev
➔ Cap 150 mg	3,870.00	60	Ofev

Restricted
Initiation – idiopathic pulmonary fibrosis
Respiratory specialist
Re-assessment required after 12 months
All of the following:
1 Patient has been diagnosed with idiopathic pulmonary fibrosis **by a multidisciplinary team including a radiologist**; and
2 Forced vital capacity is between 50% and 90% predicted; and
3 Nintedanib is to be discontinued at disease progression (See Notes); and
4 Nintedanib is not to be used in combination with subsidised pirfenidone; and
5 Any of the following:
  5.1 The patient has not previously received treatment with pirfenidone; or
  5.2 Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance; or
  5.3 Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone).

Continuation – idiopathic pulmonary fibrosis
Respiratory specialist
Re-assessment required after 12 months
All of the following:
1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2 Nintedanib is not to be used in combination with subsidised pirfenidone; and
3 Nintedanib is to be discontinued at disease progression (See Note).
Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

209 PIRFENIDONE (amended restriction criteria)

➔ Tab 801 mg	3,645.00	90	Esbriet
➔ Cap 267 mg	3,645.00	270	Esbriet

Restricted
Initiation – idiopathic pulmonary fibrosis
Respiratory specialist
Re-assessment required after 12 months
All of the following:
1 Patient has been diagnosed with idiopathic pulmonary fibrosis **by a multidisciplinary team including a radiologist**; and
2 Forced vital capacity is between 50% and 90% predicted; and
3 Pirfenidone is to be discontinued at disease progression (See Notes); and
4 Pirfenidone is not to be used in combination with subsidised nintedanib; and
5 Any of the following:
  5.1 The patient has not previously received treatment with nintedanib; or

continued...

Changes to Section H Part II – effective 1 February 2021 (continued)

continued...

5.2 Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or

5.3 Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

Continuation – idiopathic pulmonary fibrosis

Respiratory specialist

Re-assessment required after 12 months

All of the following:

1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and

2 Pirfenidone is not to be used in combination with subsidised nintedanib; and

3 Pirfenidone is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

212 AMINOPHYLLINE (↑ price)

Inj 25 mg per ml, 10 ml ampoule ..... 180.00 5 DBL Aminophylline

212 NEDOCROMIL (delisting delayed)

Aerosol inhaler 2 mg per dose

Note – delisting delayed until 1 September 2021.

SENSORY ORGANS

219 HYPROMELLOSE (new Pharmacode listing)

Eye drops 0.5% ..... 3.92 15 ml Methopt

Note – this is a new Pharmacode listing, 2603608. Pharmacode 207462 to be delisted from 1 August 2021.

SPECIAL FOODS

245 LOW ELECTROLYTE ORAL FEED (new listing)

➔ Powder 7.5 g protein, 57.6 g carbohydrate and 25.9 g fat per 100 g, 400 g can *e.g. Kindergen*

245 LOW ELECTROLYTE ORAL FEED (delisting)

➔ Powder 7.5 g protein, 59 g carbohydrate and 26.3 g fat per 100 g, 400 g can *e.g. Kindergen*

Note – Kindergen powder 7.5 g protein, 59 g carbohydrate and 26.3 g fat per 100 g, 400 g can to be delisted from 1 August 2021.

➔ Restriction

(Brand) indicates a brand example only. It is not a contracted product.

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 January 2021

ALIMENTARY TRACT AND METABOLISM

6 MESALAZINE (pack size change)
Modified release granules 1 g ..... 118.10 100 g Pentasa
Note – Pentasa modified release granules 1 g, 120 g pack to be delisted from 1 July 2021.

17 SODIUM PHENYLBUTYRATE (↑ price)
➔ Grans 483 mg per g..... 2,016.00 174 g Pheburane

21 MULTIVITAMINS (new listing)
➔ Powder vitamin A 3200 mcg with vitamin D 100 mcg, vitamin E 54.2 mg, vitamin C 400 mg, vitamin K1 108 mcg thiamine 3.2 mg, riboflavin 4.4 mg, niacin 41 mg, vitamin B6 3.6 mg, folic acid 600 mcg, vitamin B12 9 mcg, biotin 120 mcg, pantothenic acid 24 mg, choline 1250 mg and inositol 700 mg *e.g. Paediatric Seravit*

21 MULTIVITAMINS (delisting)
➔ Powder vitamin A 4200 mcg with vitamin D 155.5 mcg, vitamin E 21.4 mg, vitamin C 400 mg, vitamin K1 166 mcg thiamine 3.2 mg, riboflavin 4.4 mg, niacin 35 mg, vitamin B6 3.4 mg, folic acid 303 mcg, vitamin B12 8.6 mcg, biotin 214 mcg, pantothenic acid 17 mg, choline 350 mg and inositol 700 mg *e.g. Paediatric Seravit*
Note – Paediatric Seravit powder vitamin A 4200 mcg with vitamin D 155.5 mcg, vitamin E 21.4 mg, vitamin C 400 mg, vitamin K1 166 mcg thiamine 3.2 mg, riboflavin 4.4 mg, niacin 35 mg, vitamin B6 3.4 mg, folic acid 303 mcg, vitamin B12 8.6 mcg, biotin 214 mcg, pantothenic acid 17 mg, choline 350 mg and inositol 700 mg to be delisted from 1 July 2021.

22 THIAMINE HYDROCHLORIDE (↑ price)
Tab 50 mg..... 7.09 100 Max Health

CARDIOVASCULAR SYSTEM

43 NIFEDIPINE (brand change)
Tab long-acting 30 mg..... 34.10 100 Mylan
Tab long-acting 60 mg..... 52.81 100 Mylan
Note – Adalat Oros tab long-acting 30 mg and 60 mg to be delisted from 1 August 2021.

43 NIFEDIPINE (brand change)
Tab long-acting 10 mg..... 18.80 56 Tensipine MR10
Note – Adalat 10 tab long-acting 10 mg to be delisted from 1 August 2021.

GENITO-URINARY SYSTEM

59 CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL (↑ price and addition of HSS)
Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tablets – **1% DV Apr-21 to 2023**..... 4.98 168 **Ginet**

61 FINASTERIDE (addition of HSS)
➔ Tab 5 mg – **1% DV Apr-21 to 2023**..... 4.81 100 **Ricit**

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 January 2021 (continued)

HORMONE PREPARATIONS

72 DESMOPRESSIN (new listing)

Wafer 120 mcg	47.00	30	Minirin Melt

72 DESMOPRESSIN ACETATE (restriction criteria removed)

➔ Tab 100 mcg	25.00	30	Minirin
➔ Tab 200 mcg	54.45	30	Minirin

~~Restricted~~
~~Initiation – Nocturnal enuresis~~
~~Either:~~
~~1 The nasal forms of desmopressin are contraindicated; or~~
~~2 An enuresis alarm is contraindicated.~~
~~Note: Cranial diabetes insipidus and the nasal forms of desmopressin are contraindicated~~

INFECTIONS

74 CEFUROXIME (brand change)

Inj 750 mg vial – **1% DV Jun-21 to 2023**	8.59	10	Cefuroxime-AFT
Inj 1.5 g vial – **1% DV Jun-21 to 2023**	13.69	10	Cefuroxime-AFT

Note – Cefuroxime Actavis inj 750 mg and 1.5 g vial to be delisted from 1 June 2021.

MUSCULOSKELETAL SYSTEM

96 NEOSTIGMINE METILSULFATE WITH GLYCOPYRRONIUM BROMIDE (↑ price)

Inj 2.5 mg with glycopyrronium bromide 0.5 mg per ml, 1 ml ampoule	26.13	10	Max Health

103 CELECOXIB (↑ price)

Cap 100 mg	5.80	60	Celecoxib Pfizer
Cap 200 mg	3.30	30	Celecoxib Pfizer

104 CAPSAICIN (↓ price and addition of HSS)

➔ Crm 0.025% – **1% DV Apr-21 to 2023**	9.75	45 g	**Zostrix**

NERVOUS SYSTEM

109 CAPSAICIN (↓ price and addition of HSS)

➔ Crm 0.075% – **1% DV Apr-21 to 2023**	11.95	45 g	**Zostrix HP**

111 MORPHINE SULPHATE (delisting)

Tab long-acting 30 mg	2.85	10	Arrow-Morphine LA

Note – Arrow-Morphine LA tab long-acting 30 mg to be delisted from 1 June 2021.

112 PARACETAMOL WITH CODEINE (↑ price)

Tab paracetamol 500 mg with codeine phosphate 8 mg	26.51	1,000	Paracetamol + Codeine (Relieve)

➔ Restriction
(Brand) indicates a brand example only. It is not a contracted product.

Changes to Section H Part II – effective 1 January 2021 (continued)

113 ESCITALOPRAM (↑ price)

Tab 10 mg	1.40	28	Escitalopram-Apotex
Tab 20 mg	2.49	28	Escitalopram-Apotex

127 DISULFIRAM (↑ price)

Tab 200 mg	250.00	100	Antabuse

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

131 MITOMYCIN C (delisting)

Inj 5 mg vial	851.37	1	Teva

Note – Teva inj 5 mg vial to be delisted from 1 June 2021.

141 IMATINIB MESILATE (brand change)

Cap 100 mg – **1% DV Jun-21 to 2023**	58.23	60	**Imatinib-Rex**

Note – Imatinib-AFT cap 100 mg to be delisted from 1 June 2021.

147 BICALUTAMIDE (↑ price and addition of HSS)

Tab 50 mg – **1% DV Apr-21 to 2023**	4.21	28	**Binarex**

168 INFLIXIMAB (amended restriction criteria – affected criteria shown only)

➔ Inj 100 mg	806.00	1	Remicade

Restricted
Initiation – ~~severe~~ ulcerative colitis
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1 Patient has histologically confirmed ulcerative colitis; and
2 Either:
  2.1 Patient is 18 years or older and the Simple Clinical Colitis Activity Index (SCCAI) is greater than or equal to 4; or
  2.2 Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (PUCAI) score is greater than or equal to 65; and
3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids; and
4 Surgery (or further surgery) is considered to be clinically inappropriate.

Continuation – ~~severe~~ ulcerative colitis
Gastroenterologist
Re-assessment required after 6 months
All of the following:
1 Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and
2 Either:
  2.1 Patient is 18 years or older and the SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab; or
  2.2 Patient is under 18 years and the PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on infliximab; and
3 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 January 2021 (continued)

RESPIRATORY SYSTEM AND ALLERGIES

207	IPRATROPIUM BROMIDE (↑ price and addition of HSS)			
	Aqueous nasal spray 0.03% – **1% DV Apr-21 to 2023**	5.23	15 ml	**Univent**

SENSORY ORGANS

214	CIPROFLOXACIN (↑ price)			
	Eye drops 0.3%	12.15	5 ml	Ciprofloxacin Teva
216	NEPAFENAC (new listing)			
	Eye drops 0.3%	13.80	3 ml	Ilevro
219	BRIMONIDINE TARTRATE (↑ price)			
	Eye drops 0.2%	12.25	5 ml	Arrow-Brimonidine

VARIOUS

249	DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE (amended restriction criteria)			
	➔ Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin and 2.5 mcg pertactin in 0.5 ml syringe – **0% DV Oct-20 to 2024**	0.00	1	**Boostrix**
			10	**Boostrix**

Restricted
Initiation
Any of the following:
1 A single dose for pregnant women in the second or third trimester of each pregnancy; or; or
2 A single dose for parents or primary caregivers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days, who had not been exposed to maternal vaccination at least 14 days prior to birth; or; or
3 A course of up to four doses is funded for children from age 7 up the age of 18 years inclusive to complete full primary immunisation; or
4 An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
5 A single dose for vaccination of patients aged **from** 65 years old; or
6 A single dose for vaccination of patients aged **from** 45 years old who have not had 4 previous tetanus doses; or
7 For vaccination of previously unimmunised or partially immunised patients; or
8 For revaccination following immunosuppression; or
9 For boosting of patients with tetanus-prone wounds.

Note: ~~Tdap is not registered for patients aged less than 10 years.~~ Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

		Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 December 2020

ALIMENTARY TRACT AND METABOLISM

9 RIFAXIMIN (addition of HSS)

➔ Tab 550 mg – **1% DV Mar-21 to 2023**	625.00	56	**Xifaxan**

17 CALCIUM CARBONATE (brand change)

Tab 1.25 g (500 mg elemental) – **1% DV May-21 to 2023**	6.69	250	**Calci-Tab 500**

Note – Arrow-Calcium tab 1.25 g (500 mg elemental) to be delisted from 1 May 2021.

BLOOD AND BLOOD FORMING ORGANS

26 EMICIZUMAB (new listing)

➔ Inj 30 mg in 1 ml vial	3,570.00	1	Hemlibra
➔ Inj 60 mg in 0.4 ml vial	7,138.00	1	Hemlibra
➔ Inj 105 mg in 0.7 ml vial	12,492.00	1	Hemlibra
➔ Inj 150 mg in 1 ml vial	17,846.00	1	Hemlibra

Restricted
Initiation
Haematologist
Reassessment required after 6 months
All of the following:

1 Patient has severe congenital haemophilia A and history of bleeding and bypassing agent usage within the last six months; and
2 Either:
   2.1 Patient has had greater than or equal to 6 documented and treated spontaneous bleeds within the last 6 months if on an on-demand bypassing agent regimen; or
   2.2 Patient has had greater than or equal to 2 documented and treated spontaneous bleeds within the last 6 months if on a bypassing agent prophylaxis regimen; and
3 Patient has a high-titre inhibitor to Factor VIII (greater than or equal to 5 Bethesda units per ml) which has persisted for six months or more; and
4 There is no immediate plan for major surgery within the next 12 months; and
5 Either:
   5.1 Patient has failed immune tolerance induction (ITI) after an initial period of 12 months; or
   5.2 The Haemophilia Treaters Group considers the patient is not a suitable candidate for ITI; and
6 Treatment is to be administered at a maximum dose of 3 mg/kg weekly for 4 weeks followed by the equivalent of 1.5 mg/kg weekly.

Continuation
Haematologist
Reassessment required after 6 months
Both:

1 Patient has had no more than two spontaneous and clinically significant treated bleeds after the end of the loading dose period (i.e. after the first four weeks of treatment until the end of the 24-week treatment period); and
2 The treatment remains appropriate and the patient is benefiting from treatment.

36 WATER (delisting)

Inj 5 ml ampoule	7.00	50	InterPharma
Inj 20 ml ampoule	7.50	30	InterPharma

Note – InterPharma inj 5 ml and 20 ml ampoule to be delisted from 1 June 2021.

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 December 2020 (continued)

DERMATOLOGICALS

56 PIMECROLIMUS (new listing)
➔ Crm 1% – **1% DV Mar-21 to 2023** ..... 28.50 15 g **Elidel**

Restricted
Initiation
Dermatologist, paediatrician or ophthalmologist
Both:
1 Patient has atopic dermatitis on the eyelid; and
2 Patient has at least one of the following contraindications to topical corticosteroids: periorificial dermatitis, rosacea, documented epidermal atrophy, documented allergy to topical corticosteroids, cataracts, glaucoma, or raised intraocular pressure.

HORMONE PREPARATIONS

66 GOSERELIN (brand change)
Implant 3.6 mg, syringe – **1% DV May-21 to 2023** ..... 65.68 1 **Teva**
Implant 10.8 mg, syringe – **1% DV May-21 to 2023** ..... 122.37 1 **Teva**
Note – Zoladex implant 3.6 mg and 10.8 mg, syringe to be delisted from 1 May 2021.

INFECTIONS

72 TOBRAMYCIN (brand change)
➔ Solution for inhalation 60 mg per ml, 5 ml
– **1% DV May-21 to 2023** ..... 395.00 56 dose **Tobramycin BNM**
Note – TOBI solution for inhalation 60 mg per ml, 5 ml to be delisted from 1 May 2021.

93 PEGYLATED INTERFERON ALFA-2A (amended restriction criteria – new criteria shown only)
➔ Inj 180 mcg prefilled syringe ..... 500.00 4 Pegasys

Restricted
Initiation - ocular surface squamous neoplasia
Ophthalmologist
Reassessment required after 12 months
Patient has ocular surface squamous neoplasia *

Continuation - ocular surface squamous neoplasia
Ophthalmologist
Reassessment required after 12 months
The treatment remains appropriate and patient is benefitting from treatment.
Note: Indications marked with * are unapproved indications

NERVOUS SYSTEM

113 PARALDEHYDE (new listing)
Soln 97%

117 CYCLIZINE LACTATE (brand change)
Inj 50 mg per ml, 1 ml ampoule – **1% DV May-21 to 2022** ..... 21.53 10 **Hameln**
Note – Nausicalm inj 50 mg per ml, 1 ml ampoule to be delisted from 1 May 2021.

Changes to Section H Part II – effective 1 December 2020 (continued)

127 BUPROPION HYDROCHLORIDE (addition of HSS)
Tab modified-release 150 mg – **1% DV Mar-21 to 2023** ..... 11.00 30 **Zyban**

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

131 MITOMYCIN C (new listing)
Inj 20 mg vial ..... 3,275.00 1 Teva

135 PEGASPARGASE (amended restriction criteria)
➔ Inj 750 iu per ml, 5 ml vial ..... 3,455.00 1 Oncaspar LYO

Restricted
Initiation – Newly diagnosed ALL
Limited to 12 months treatment
Both ~~All of the following~~:
1 The patient has newly diagnosed acute lymphoblastic leukaemia; and.
2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol; ~~and~~
~~3 Treatment is with curative intent.~~

Initiation – Relapsed ALL
Limited to 12 months treatment
Both ~~All of the following~~:
1 The patient has relapsed acute lymphoblastic leukaemia; and
2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol; ~~and~~
~~3 Treatment is with curative intent.~~

Initiation – Lymphoma
Limited to 12 months treatment
Patient has lymphoma requiring L-asparaginase containing protocol (e.g. SMILE)

141 IMATINIB MESILATE (brand change)
Cap 400 mg – **1% DV Jun-21 to 2023** ..... 84.79 30 **Imatinib-Rex**
Note – Imatinib-AFT cap 400 mg to be delisted from 1 June 2021.

145 DOCETAXEL (delisting)
Inj 10 mg per ml, 2 ml vial ..... 12.40 1 DBL Docetaxel
Note – DBL Docetaxel inj 10 mg per ml, 2 ml vial to be delisted from 1 June 2021.

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 December 2020 (continued)

150 ETANERCEPT (amended restriction criteria – affected criteria shown only)

➔ Inj 25 mg vial – **5% DV Sep-19 to 2024**	690.00	4	**Enbrel**
➔ Inj 50 mg autoinjector – **5% DV Sep-19 to 2024**	1,050.00	4	**Enbrel**
➔ Inj 50 mg syringe – **5% DV Sep-19 to 2024**	1,050.00	4	**Enbrel**

Initiation - **polyarticular course** juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for adalimumab for **polyarticular course** juvenile idiopathic arthritis (JIA); and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from adalimumab; or
1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for **polyarticular course** JIA; or
2 All of the following:
~~2.1 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and~~
2.1~~2~~ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.2~~3~~ Patient has had ~~severe active~~ polyarticular course JIA for 6 months duration or longer; and
2.3 Any of the following:
2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.
~~2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m^2 weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and~~
~~2.5 Both:~~
~~2.5.1 Either:~~
~~2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or~~
~~2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and~~
~~2.5.2 Physician's global assessment indicating severe disease.~~

Initiation - oligoarticular course juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA); and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from adalimumab; or
1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA; or

continued...

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

2 All of the following:
- **2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and**
- **2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and**
- **2.3 Any of the following:**
  - **2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or**
  - **2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose); or**
  - **2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.**

Continuation – **polyarticular course** juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Both:
1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
- 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Continuation – oligoarticular course juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Both:
1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
- **2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or**
- **2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.**

156 ADALIMUMAB (amended restriction criteria – affected criteria shown only)

➔ Inj 20 mg per 0.4 ml syringe	1,599.96	2	Humira
➔ Inj 40 mg per 0.8 ml pen	1,599.96	2	HumiraPen
➔ Inj 40 mg per 0.8 ml syringe	1,599.96	2	Humira

Restricted
Initiation – **polyarticular course** juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Either:
1 Both:
- 1.1 The patient has had an initial Special Authority approval for etanercept for **polyarticular course** juvenile idiopathic arthritis (JIA); and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
  - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for **polyarticular course** JIA; or

continued...

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

2 All of the following:

~~2.1 Patient diagnosed with JIA; and~~

2.1~~2~~ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2.2~~3~~ Patient has had ~~severe active~~ polyarticular course JIA for 6 months duration or longer; and

2.3 Any of the following:

2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or

2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or

2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

~~2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and~~

~~2.5 Both:~~

~~2.5.1 Either:~~

~~2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or~~

~~2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and~~

~~2.5.2 Physician's global assessment indicating severe disease.~~

Initiation – oligoarticular course juvenile idiopathic arthritis
Rheumatologist or named specialist
Re-assessment required after 6 months
Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from etanercept; or

1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for oligoarticular course JIA; or

2 All of the following:

2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and

2.3 Any of the following:

2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or

2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose); or

2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.

Continuation - **polyarticular course** juvenile idiopathic arthritis
Rheumatologist or named specialist
Reassessment required after 6 months
Both:

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

continued...

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

2 Either:
- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
- 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Continuation – oligoarticular course juvenile idiopathic arthritis
Rheumatologist or named specialist
Reassessment required after 6 months
Both:

1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
- **2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or**
- **2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.**

179 RITUXIMAB (MABTHERA) (amended restriction criteria)

➔ Inj 10 mg per ml, 10 ml vial	1,075.50	2	Mabthera
➔ Inj 10 mg per ml, 50 ml vial	2,688.30	1	Mabthera

Restricted

~~Initiation – haemophilia with inhibitors~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – haemophilia with inhibitors~~
~~Haematologist~~
~~All of the following:~~
~~1 Patient was previously treated with rituximab for haemophilia with inhibitors; and~~
~~2 An initial response lasting at least 12 months was demonstrated; and~~
~~3 Patient now requires repeat treatment.~~

~~Initiation – post-transplant~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – post-transplant~~
~~All of the following:~~
~~1 The patient has had a rituximab treatment-free interval of 12 months or more; and~~
~~2 The patient has B-cell post-transplant lymphoproliferative disorder*; and~~
~~3 To be used for no more than 6 treatment cycles.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – indolent, low-grade lymphomas or hairy cell leukaemia*~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – indolent, low-grade lymphomas or hairy cell leukaemia*~~
~~Re-assessment required after 9 months~~
~~All of the following:~~
~~1 The patient has had a rituximab treatment-free interval of 12 months or more; and~~
~~2 The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and~~
~~3 To be used for no more than 6 treatment cycles.~~
~~Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/ Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.~~

continued...

	Price (ex man. Excl. GST) $	Per	Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

~~Initiation – aggressive CD20 positive NHL~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – aggressive CD20 positive NHL~~
~~All of the following:~~
~~1 The patient has had a rituximab treatment-free interval of 12 months or more; and~~
~~2 The patient has relapsed refractory/aggressive CD20 positive NHL; and~~
~~3 To be used with a multi-agent chemotherapy regimen given with curative intent; and~~
~~4 To be used for a maximum of 4 treatment cycles.~~
~~Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.~~

~~Initiation – Chronic lymphocytic leukaemia~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Chronic lymphocytic leukaemia~~
~~Re-assessment required after 12 months~~
~~Both:~~
~~1 Either:~~
~~1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or~~
~~1.2 All of the following:~~
~~1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and~~
~~1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and~~
~~1.2.3 The patient does not have chromosome 17p deletion CLL; and~~
~~1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustin; and~~
~~2 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles.~~
~~Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.~~

Initiation – rheumatoid arthritis - prior TNF inhibitor use
Rheumatologist
Limited to 4 months treatment
All of the following:
1 Both:
1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and
2 Either:
2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

continued...

➔ Restriction
(Brand) indicates a brand example only. It is not a contracted product.

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

Initiation – rheumatoid arthritis - TNF inhibitors contraindicated
Rheumatologist
Limited to 4 months treatment
All of the following:

1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
2 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
5 Any of the following:
  5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of cyclosporin; or
  5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
6 Either:
  6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
  6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
7 Either:
  7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and
8 Either:
  8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Continuation – rheumatoid arthritis - re-treatment in 'partial responders' to rituximab
Rheumatologist
Re-assessment required after 4 months
All of the following:

1 Any of the following:
  1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
3 Either:
  3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or

continued...

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Continuation – rheumatoid arthritis - re-treatment in 'responders' to rituximab
Rheumatologist
Re-assessment required after 4 months
All of the following:

1 Either:
- 1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and

2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and

3 Either:
- 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

~~Initiation – severe cold haemagglutinin disease (CHAD)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – severe cold haemagglutinin disease (CHAD)~~
~~Haematologist~~
~~Re-assessment required after 8 weeks~~
~~Either:~~

~~1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or~~

~~2 All of the following:~~
- ~~2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and~~
- ~~2.2 An initial response lasting at least 12 months was demonstrated; and~~
- ~~2.3 Patient now requires repeat treatment.~~

~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – warm autoimmune haemolytic anaemia (warm AIHA)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – warm autoimmune haemolytic anaemia (warm AIHA)~~
~~Haematologist~~
~~Re-assessment required after 8 weeks~~
~~Either:~~

~~1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or~~

~~2 All of the following:~~
- ~~2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*; and~~
- ~~2.2 An initial response lasting at least 12 months was demonstrated; and~~
- ~~2.3 Patient now requires repeat treatment.~~

~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – immune thrombocytopenic purpura (ITP)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

continued...

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

~~Continuation – immune thrombocytopenic purpura (ITP)~~
~~Haematologist~~
~~Re-assessment required after 8 weeks~~
~~Either:~~
~~1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or~~
~~2 All of the following:~~
~~2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and~~
~~2.2 An initial response lasting at least 12 months was demonstrated; and~~
~~2.3 Patient now requires repeat treatment.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – thrombotic thrombocytopenic purpura (TTP)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – thrombotic thrombocytopenic purpura (TTP)~~
~~Haematologist~~
~~Re-assessment required after 8 weeks~~
~~All of the following:~~
~~1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*; and~~
~~2 An initial response lasting at least 12 months was demonstrated; and~~
~~3 Patient now requires repeat treatment; and~~
~~4 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – pure red cell aplasia (PRCA)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – pure red cell aplasia (PRCA)~~
~~Haematologist~~
~~Re-assessment required after 6 weeks~~
~~Patient was previously treated with rituximab for pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – ANCA associated vasculitis~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – ANCA associated vasculitis~~
~~Re-assessment required after 8 weeks~~
~~All of the following:~~
~~1 Patient has been diagnosed with ANCA associated vasculitis*; and~~
~~2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and~~
~~3 The total rituximab dose would not exceed the equivalent of 375 mg/m² of body-surface area per week for a total of 4 weeks.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – treatment refractory systemic lupus erythematosus (SLE)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – treatment refractory systemic lupus erythematosus (SLE)~~
~~Rheumatologist or nephrologist~~
~~All of the following:~~
~~1 Patient's SLE* achieved at least a partial response to the previous round of prior rituximab treatment; and~~

continued...

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

~~2 The disease has subsequently relapsed; and~~
~~3 Maximum of two 1000 mg infusions of rituximab.~~
~~Note: Indications marked with * are unapproved indications.~~

~~Initiation – Antibody-mediated renal transplant rejection~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Initiation – ABO-incompatible renal transplant~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Initiation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)~~
~~Nephrologist~~
~~Re-assessment required after 8 weeks~~
~~All of the following:~~
~~1 Patient who was previously treated with rituximab for nephrotic syndrome*; and~~
~~2 Treatment with rituximab was previously successful and has demonstrated sustained response for > 6 months, but the condition has relapsed and the patient now requires repeat treatment; and~~
~~3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.~~
~~Note: Indications marked with a * are unapproved indications.~~

~~Initiation – Steroid resistant nephrotic syndrome (SRNS)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Steroid resistant nephrotic syndrome (SRNS)~~
~~Nephrologist~~
~~Re-assessment required after 8 weeks~~
~~All of the following:~~
~~1 Patient who was previously treated with rituximab for nephrotic syndrome*; and~~
~~2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and~~
~~3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.~~
~~Note: Indications marked with a * are unapproved indications.~~

~~Initiation – Neuromyelitis Optica Spectrum Disorder (NMOSD)~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Neuromyelitis Optica Spectrum Disorder (NMOSD)~~
~~Relevant specialist or medical practitioner on the recommendation of a Relevant specialist~~
~~Re-assessment required after 2 years~~
~~All of the following:~~
~~1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m^2 administered weekly for four weeks; and~~
~~2 The patients has responded to the most recent course of rituximab; and~~
~~3 The patient has not received rituximab in the previous 6 months.~~

~~Initiation – Severe Refractory Myasthenia Gravis~~
~~No new patient can start on rituximab (Mabthera brand) under this Initiation criteria from 1 March 2020.~~

~~Continuation – Severe Refractory Myasthenia Gravis~~
~~Neurologist or medical practitioner on the recommendation of a Neurologist~~
~~Re-assessment required after 2 years~~
~~All of the following:~~

continued...

Changes to Section H Part II – effective 1 December 2020 (continued)

continued...

~~1 One of the following dose regimens is to be used: 375 mg/m² of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and~~
~~2 An initial response lasting at least 12 months was demonstrated; and~~
~~3 Either:~~
~~3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or~~
~~3.2 Both:~~
~~3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and~~
~~3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.~~

195 TOCILIZUMAB (amended restriction criteria – affected criteria shown only)

➔ Inj 20 mg per ml, 4 ml vial	220.00	1	Actemra
➔ Inj 20 mg per ml, 10 ml vial	550.00	1	Actemra
➔ Inj 20 mg per ml, 20 ml vial	1,100.00	1	Actemra

Initiation – polyarticular juvenile idiopathic arthritis
Rheumatologist or Practitioner on the recommendation of a rheumatologist
Re-assessment required after 4 months
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for **polyarticular course** juvenile idiopathic arthritis (JIA); and
1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or
2 All of the following:
2.1 Treatment with a tumour necrosis factor alpha inhibitor is contraindicated; and
2.2 Patient has had ~~severe active~~ polyarticular course JIA for 6 months duration or longer; and
~~2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and~~
2.3 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.4 Any of the following:
2.4.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.4.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.4.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.
~~2.5 Both:~~
~~2.5.1 Either:~~
~~2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or~~
~~2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and~~
~~2.5.2 Physician's global assessment indicating severe disease~~

Changes to Section H Part II – effective 1 December 2020 (continued)

RESPIRATORY SYSTEM AND ALLERGIES

212 DORNASE ALFA (amended restriction criteria – affected criteria shown only)
➔ Nebuliser soln 2.5 mg per 2.5 ml ampoule ..... 250.00 6 Pulmozyme

Restricted
Initiation - cystic fibrosis
~~1 The patient has cystic fibrosis and has been approved by the Cystic Fibrosis Panel~~
Respiratory physician or paediatrician
Reassessment required after 12 months
All of the following:
1 Patient has a confirmed diagnosis of cystic fibrosis; and
2 Patient has previously undergone a trial with, or is currently being treated with, hypertonic saline; and
3 Any of the following:
3.1 Patient has required one or more hospital inpatient respiratory admissions in the previous 12 month period; or
3.2 Patient has had 3 exacerbations due to CF, requiring oral or intravenous (IV) antibiotics in in the previous 12 month period; or
3.3 Patient has had 1 exacerbation due to CF, requiring oral or IV antibiotics in the previous 12 month period and a Brasfield score of <22/25; or
3.4 Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA).

Continuation - cystic fibrosis
Respiratory physician or paediatrician
The treatment remains appropriate and the patient continues to benefit from treatment.

SPECIAL FOODS

236 AMINO ACID FORMULA (WITHOUT PHENYLALANINE) (new listing)
➔ Powder 13.1 g protein, 50.1 g carbohydrate,
23 g fat and 5.3 g fibre per 100 g, 400 g can *e.g. PKU Anamix Infant*

236 AMINO ACID FORMULA (WITHOUT PHENYLALANINE) (delisting)
➔ Powder 13.1 g protein, 49.5 g carbohydrate, 23 g fat
and 5.3 g fibre per 100 g, 400 g can *e.g. PKU Anamix Infant*
Note – PKU Anamix Infant powder 13.1 g protein, 49.5 g carbohydrate, 23 g fat and 5.3 g fibre per 100 g, 400 g can to be delisted from 1 June 2021.

242 EXTENSIVELY HYDROLYSED FORMULA (amended brand name)
➔ Powder 1.6 g protein, 7.5 g carbohydrate and
3.1 g fat per 100 ml, 900 g can ..... 30.42 900 g **Aptamil** AllerPro **SYNEO** 1

➔ Powder 1.6 g protein, 7.8 g carbohydrate and
3.2 g fat per 100 ml, 900 g can ..... 30.42 900 g **Aptamil** AllerPro **SYNEO** 2

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New Zealand
Permit No. 478

Permit

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