

Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

July 2020

Cumulative for April, May, June and July 2020

The logo for PHARMAC, featuring the word "PHARMAC" in a bold, uppercase, sans-serif font, with "TE PĀTAKA WHAIORANGA" in a smaller, uppercase, sans-serif font below it. The logo is centered within a white circle that overlaps a background of stylized, concentric, wavy lines in shades of gray and white.

PHARMAC
TE PĀTAKA WHAIORANGA

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Summary of decisions

EFFECTIVE 1 JULY 2020

- Acitretin (Novatretin) cap 10 mg and 25 mg – addition of HSS
- Amino acid formula powder 1.95 g protein, 8.1 g carbohydrate and 3.5 g fat per 100 ml, 400 g can (e.g. Neocate); powder 13 g protein, 49 g carbohydrate and 23 g fat per 100 g, 400 g can (e.g. Neocate SYNEO unflavoured); powder 13.3 g protein, 56 g carbohydrate and 22 g fat per 100 g, 400 g can (e.g. Neocate Junior Unflavoured); powder 13.5 g protein, 52 g carbohydrate and 24.5 g fat per 100 g, can, 400 g (Neocate Gold (Unflavoured)); powder 14.8 g protein, 51.4 g carbohydrate and 23 g fat per 100 g, can, 400 g (Neocate Junior Vanilla); powder 15 g protein, 56 g carbohydrate and 20 g fat per 100 g, can, 400 g (Alfamino Junior); powder 2.2 g protein, 7.8 g carbohydrate and 3.4 g fat per 100 ml, can, 400 g (Elecare LCP (Unflavoured)); powder 2.2 g protein, 7.8 g carbohydrate and 3.4 g fat per 100 ml, can, 400 g (Elecare (Unflavoured and Vanilla)) – amended restriction criteria
- Amorolfine (MycONail) nail soln 5%, 5 ml – price decrease and addition of HSS
- Atomoxetine (Generic Partners) cap 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg – new listing, addition of HSS and restrictions removed
- Atomoxetine (Strattera) cap 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg – to be delisted 1 September 2020
- Atropine sulphate (Atropt) eye drops 1%, 15 ml – addition of HSS
- Bacillus calmette-guerin vaccine (BCG Vaccine) inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial Danish strain 1331, live attenuated, vial with diluent – addition of HSS
- Benzatropine mesylate (Phebra) inj 1 mg per ml, 2 ml ampoule – new listing and addition of HSS
- Benzatropine mesylate (Cogentin) inj 1 mg per ml, 2 ml ampoule – to be delisted 1 December 2020
- Budesonide (SteroClear) nasal spray 50 mcg and 100 mcg per dose, 200 dose – price decrease and addition of HSS
- Bupivacaine hydrochloride inj 5 mg per ml, 4 ml ampoule (Marcaïn Isobaric) and inj 2.5 mg per ml, 100 ml bag (Marcaïn) – addition of HSS
- Calcipotriol (Daivonex) oint 50 mcg per g, 120 g – new pack size listing
- Calcipotriol (Daivonex) oint 50 mcg per g, 100 g – to be delisted 1 January 2021
- Ceftazidime (Ceftazidime-AFT) inj 1 g vial – new listing and addition of HSS
- Ceftazidime (Ceftazidime Mylan) inj 1 g vial – to be delisted 1 December 2020

Summary of decisions – effective 1 July 2020 (continued)

- Diphtheria, tetanus and pertussis vaccine (Boostrix) 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 – amended restriction criteria, presentation description and addition of HSS
 - Diphtheria, tetanus, pertussis and polio vaccine (Infanrix IPV) inj 30 IU diphtheria toxoid with 30IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5 ml syringe – amended presentation description and addition of HSS
 - Diphtheria, tetanus, pertussis, polio, hepatitis B and Haemophilus influenzae type B vaccine (Infanrix-hexa) inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-antigen units poliomyelitis virus, 10 mcg hepatitis B surface antigen in 0.5 ml syringe (1) and inj 10 mcg haemophilus influenzae type B vaccine vial – amended presentation description and addition of HSS
 - Docusate sodium (Coloxyl) tab 50 mg and 120 mg – addition of HSS
 - Emulsifying ointment (Jaychem) oint BP, 100 g – addition of HSS
 - Ephedrine (Max Health) inj 30 mg per ml, 1 ml ampoule – price decrease and addition of HSS
 - Ezetimibe (Ezetimibe Sandoz) tab 10 mg – price decrease and addition of HSS
 - Glycerol (healthE Glycerol BP Liquid) liq, 500 ml – price decrease and addition of HSS
 - Hepatitis A vaccine inj 720 ELISA units in 0.5 ml syringe (Havrix Junior) and inj 1440 ELISA units in 1 ml syringe (Havrix) – addition of HSS
 - Human papillomavirus (6, 11, 16, 18, 31, 33, 45, 52 and 58) vaccine [HPV] (Gardasil 9) inj 270 mcg in 0.5 ml syringe – addition of HSS
 - Hydrocortisone and paraffin liquid and lanolin (DP Lotn HC) lotn 1% with paraffin liquid 15.9% and lanolin 0.6%, 250 ml – addition of HSS
 - Hydrocortisone butyrate (Locoid Lipocream) crm 0.1%, 30 g – to be delisted 1 February 2021
 - Hyoscine butylbromide (Buscopan) tab 10 mg – price decrease and addition of HSS
 - Interferon alfa-2a inj 3 m, 6 m and 9 m prefilled syringe – to be delisted 1 December 2020
 - Leflunomide (Arava) tab 10 mg and 20 mg – new listing and addition of HSS
 - Leflunomide (Apo-Leflunomide) tab 10 mg and 20 mg – to be delisted 1 December 2020
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Summary of decisions – effective 1 July 2020 (continued)

- Macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride (Molaxole) powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg – price decrease and addition of HSS
- Measles, mumps and rubella vaccine (Priorix) injection, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml – addition of HSS
- Meningococcal (A, C, Y and W-135) conjugate vaccine (Menactra) inj 4 mcg or each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial – addition of HSS
- Meningococcal C conjugate vaccine (Neisvac-C) inj 10 mcg in 0.5 ml syringe – amended restriction criteria
- Methotrexate (Methotrexate Ebewe) inj 100 mg per ml, 50 ml vial – addition of HSS
- Metoclopramide hydrochloride (Metoclopramide Actavis 10) tab 10 mg – addition of HSS
- Mycophenolate mofetil (Cellcept) tab 500 mg and cap 250 mg – increase price
- Nedocromil aerosol inhaler 2 mg per dose – to be delisted 1 February 2021
- Nystatin (Nilstat) oral liquid 100,000 u per ml, 24 ml – price decrease and addition of HSS
- Nystatin (Nilstat) vaginal crm 100,000 u per 5 g with applicator(s), 75 g – price decrease and addition of HSS
- Oestriol (Ovestin) crm 1 mg per g with applicator, 15 g and pessaries 500 mcg – addition of HSS
- Ondansetron (Ondansetron ODT-DRLA) tab dispersible 4 mg and 8 mg – price decrease and addition of HSS
- Oxybutynin (Apo-Oxybutynin) tab 5 mg – price increase
- Pegylated interferon alfa-2a (Pegasys) inj 180 mcg prefilled syringe – amended restriction criteria
- Pneumococcal (PCV10) conjugate vaccine (Synflorix) inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml prefilled syringe – amended restriction criteria and addition of HSS
- Pneumococcal (PCV13) conjugate vaccine (Prevenar 13) inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5 ml syringe – amended restriction criteria

Summary of decisions – effective 1 July 2020 (continued)

- Pneumococcal (PPV23) polysaccharide vaccine (Pneumovax 23) inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype – addition of HSS
 - Poliomyelitis vaccine (IPOL) inj 80 D-antigen units in 0.5 ml syringe – addition of HSS
 - Potassium iodate (NeuroTabs) tab 253 mcg (150 mcg elemental iodine) – price decrease and addition of HSS
 - Pyridoxine hydrochloride (Vitamin B6 25) tab 25 mg – addition of HSS
 - Remifentanyl (Remifentanyl-AFT) inj 1 mg and 2 mg vial – addition of HSS
 - Rituximab (Riximyo) inj 10 mg per ml, 10 ml and 50 ml vial – amended restriction criteria
 - Rizatriptan (Rizamelt) tab orodispersible 10 mg – price decrease and addition of HSS
 - Rotavirus oral vaccine (Rotarix) oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator – addition of HSS
 - Sodium citro-tartrate (Ural) grans eff 4 g sachet – price decrease and addition of HSS
 - Sodium cromoglicate aerosol inhaler 5 mg per dose – to be delisted 1 May 2021
 - Sucrose oral liq 66.7% (preservative free) – new listing
 - Teicoplanin (Teicoplanin Mylan) inj 400 mg vial – new listing and addition of HSS
 - Terazosin (Actavis) tab 1 mg – to be delisted 1 October 2020
 - Tramadol hydrochloride (Tramal 50) inj 50 mg per ml, 1 ml ampoule – addition of HSS
 - Tramadol hydrochloride (Tramal 100) inj 50 mg per ml, 2 ml ampoule – price decrease and addition of HSS
 - Tuberculin PPD [mantoux] test (Tubersol) inj 5 TU per 0.1 ml, 1 ml vial – addition of HSS
 - Ursodeoxycholic acid (Ursosan) cap 250 mg – price decrease and addition of HSS
 - Vancomycin (Mylan) inj 500 mg vial – price decrease and addition of HSS
 - Varicella vaccine [chickenpox vaccine] (Varivax) inj 1350 PFU prefilled syringe – new listing and addition of HSS
 - Varicella vaccine [chickenpox vaccine] (Varilrix) inj 2000 PFU prefilled syringe plus vial – to be delisted 1 October 2020.
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		Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Section H changes to Part II

Effective 1 July 2020

ALIMENTARY TRACT AND METABOLISM

7	HYOSCINE BUTYLBROMIDE (↓ price and addition of HSS) Tab 10 mg – 1% DV Oct-20 to 2023	6.35	100	Buscopan
11	URSODEOXYCHOLIC ACID (↓ price and addition of HSS) → Cap 250 mg – 1% DV Oct-20 to 2023	32.95	100	Ursosan
12	DOCUSATE SODIUM (addition of HSS) Tab 50 mg – 1% DV Oct-20 to 2023	2.31	100	Coloxyl
	Tab 120 mg – 1% DV Oct-20 to 2023	3.13	100	Coloxyl
13	MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BICARBONATE AND SODIUM CHLORIDE (↓ price and addition of HSS) Powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg – 1% DV Oct-20 to 2023	6.70	30	Molaxole
18	POTASSIUM IODATE (↓ price and addition of HSS) Tab 253 mcg (150 mcg elemental iodine) – 1% DV Oct-20 to 2023	4.58	90	NeuroTabs
19	NYSTATIN (↓ price and addition of HSS) Oral liquid 100,000 u per ml – 1% DV Oct-20 to 2023	1.76	24 ml	Nilstat
22	PYRIDOXINE HYDROCHLORIDE (addition of HSS) Tab 25 mg – 1% DV Oct-20 to 2023	2.70	90	Vitamin B6 25

CARDIOVASCULAR SYSTEM

40	TERAZOSIN (delisting) Tab 1 mg	0.59	28	Actavis
	Note – Actavis tab 1 mg to be delisted from 1 October 2020.			
45	EZETIMIBE (↓ price and addition of HSS) → Tab 10 mg – 1% DV Oct-20 to 2023	1.95	30	Ezetimibe Sandoz
47	EPHEDRINE (↓ price and addition of HSS) Inj 30 mg per ml, 1 ml ampoule – 1% DV Oct-20 to 2023	30.63	10	Max Health

DERMATOLOGICALS

52	AMOROLFINE (↓ price and addition of HSS) Nail soln 5% – 1% DV Oct-20 to 2023	14.93	5 ml	MycoNail
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		Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

54	EMULSIFYING OINTMENT (addition of HSS) Oint BP – 1% DV Oct-20 to 2023 1.84	100 g		Jaychem
	Note: DV limit applies to pack sizes of less than 200 g.			
55	HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN (addition of HSS) Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% – 1% DV Oct-20 to 2023 10.57	250 ml		DP Lotn HC
55	HYDROCORTISONE BUTYRATE (delisting) Crm 0.1% 3.42	30 g		Locoid Lipocream
	Note – Locoid Lipocream crm 0.1% to be delisted from 1 February 2021.			
56	ACITRETIN (addition of HSS) Cap 10 mg – 1% DV Oct-20 to 2023 17.86	60		Novatretin
	Cap 25 mg – 1% DV Oct-20 to 2023 41.36	60		Novatretin
56	CALCIPOTRIOL (pack size change) Oint 50 mcg per g 40.00	120 g		Daivonex
	Note – Daivonex oint 50 mcg per g, 100 g to be delisted from 1 January 2021.			

GENITO-URINARY SYSTEM

58	NYSTATIN (↓ price and addition of HSS) Vaginal crm 100,000 u per 5 g with applicator(s) – 1% DV Oct-20 to 2023 4.00	75 g		Nilstat
60	OESTRIOL (addition of HSS) Crm 1 mg per g with applicator – 1% DV Oct-20 to 2023 6.62	15 g		Ovestin
	Pessaries 500 mcg – 1% DV Oct-20 to 2023 6.86	15		Ovestin
61	SODIUM CITRO-TARTRATE (↓ price and addition of HSS) Grans eff 4 g sachets – 1% DV Oct-20 to 2023 2.22	28		Ural
61	OXYBUTYNIN (↑ price) Tab 5 mg 11.70	500		Apo-Oxybutynin

INFECTIONS

73	CEFTAZIDIME (brand change) → Inj 1 g vial – 1% DV Dec-20 to 2023 2.69	1		Ceftazidime-AFT
	Note – Ceftazidime Mylan inj 1 g vial to be delisted from 1 December 2020.			
79	TEICOPLANIN (new listing and addition of HSS) → Inj 400 mg vial – 1% DV Jul-20 to 2021 56.50	1		Teicoplanin Mylan
79	VANCOMYCIN (↓ price and addition of HSS) → Inj 500 mg vial – 1% DV Oct-20 to 2023 2.35	1		Mylan

→ Restriction

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

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

- 92 INTERFERON ALFA-2A (delisting)
 Inj 3 m iu prefilled syringe
 Inj 6 m iu prefilled syringe
 Inj 9 m iu prefilled syringe
 Note – interferon alfa-2a inj 3 m, 6 m and 9 m prefilled syringe to be delisted from 1 December 2020.

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

Restricted

Initiation – myeloproliferative disorder or cutaneous T cell lymphoma

Reassessment required after 12 months

Any of the following:

- 1 Patient has a cutaneous T cell lymphoma*; or
- 2 All of the following:
 - 2.1 Patient has a myeloproliferative disorder*; and
 - 2.2 Patient is intolerant of hydroxyurea; and
 - 2.3 Treatment with anagrelide and busulfan is not clinically appropriate; or
- 3 Both:
 - 3.1 Patient has a myeloproliferative disorder; and
 - 3.2 Patient is pregnant, planning pregnancy or lactating.

Continuation – myeloproliferative disorder or cutaneous T cell lymphoma

Reassessment required after 12 months

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and patient is benefitting from treatment; and;
- 3 Either:
 - 3.1 Patient has a cutaneous T cell lymphoma*; or
 - 3.2 Both
 - 3.2.1 Patient has a myeloproliferative disorder*; and
 - 3.2.2 Either:
 - 3.2.2.1 Remains intolerant of hydroxyurea and treatment with anagrelide and busulfan remains clinically inappropriate; or
 - 3.2.2.2 Patient is pregnant, planning pregnancy or lactating.

Note: Indications marked with * are unapproved indications

MUSCULOSKELETAL SYSTEM

- 94 LEFLUNOMIDE (brand change)
 Tab 10 mg – **1% DV Dec-20 to 2023** 6.00 30 **Arava**
 Tab 20 mg – **1% DV Dec-20 to 2023** 6.00 30 **Arava**
 Note – Apo-Leflunomide tab 10 mg and 20 mg to be delisted 1 December 2020.

NERVOUS SYSTEM

- 103 BENZATROPINE MESYLATE (brand change)
 Inj 1 mg per ml, 2 ml ampoule – **1% DV Dec-20 to 2023** 95.00 5 **Phebra**
 Note – Cogentin inj 1 mg per ml, 2 ml ampoule to be delisted from 1 December 2020.

		Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

105	BUPIVACAINE HYDROCHLORIDE (addition of HSS) Inj 5 mg per ml, 4 ml ampoule – 1% DV Oct-20 to 2023 50.00 Inj 2.5 mg per ml, 100 ml bag – 1% DV Oct-20 to 2023 150.00	5 5	Marcaïn Isobaric Marcaïn
108	SUCROSE (new listing) → Oral liq 66.7% (preservative free) Restricted Initiation For use in neonatal patients only.		
110	REMIFENTANIL (addition of HSS) Inj 1 mg vial – 1% DV Oct-20 to 2023 13.95 Inj 2 mg vial – 1% DV Oct-20 to 2023 19.95	5 5	Remifentanil-AFT Remifentanil-AFT
110	TRAMADOL HYDROCHLORIDE (addition of HSS) Inj 50 mg per ml, 1 ml ampoule – 1% DV Oct-20 to 2023 4.50	5	Tramal 50
110	TRAMADOL HYDROCHLORIDE (↓ price and addition of HSS) Inj 50 mg per ml, 2 ml ampoule – 1% DV Oct-20 to 2023 3.83	5	Tramal 100
115	RIZATRIPTAN (↓ price and addition of HSS) Tab orodispersible 10 mg – 1% DV Oct-20 to 2023 3.65	30	Rizamelt
116	METOCLOPRAMIDE HYDROCHLORIDE (addition of HSS) Tab 10 mg – 1% DV Oct-20 to 2023 1.30	100	Metoclopramide Actavis 10
116	ONDANSETRON (↓ price and addition of HSS) Tab dispersible 4 mg – 1% DV Oct-20 to 2023 0.76 Tab dispersible 8 mg – 1% DV Oct-20 to 2023 1.13	10 10	Ondansetron ODT-DRLA Ondansetron ODT-DRLA
123	ATOMOXETINE (brand change and restrictions removed) → Cap 10 mg – 1% DV Sep-20 to 2022 18.41 → Cap 18 mg – 1% DV Sep-20 to 2022 27.06 → Cap 25 mg – 1% DV Sep-20 to 2022 29.22 → Cap 40 mg – 1% DV Sep-20 to 2022 29.22 → Cap 60 mg – 1% DV Sep-20 to 2022 46.51 → Cap 80 mg – 1% DV Sep-20 to 2022 56.45 → Cap 100 mg – 1% DV Sep-20 to 2022 58.48	28 28 28 28 28 28 28	Generic Partners Generic Partners Generic Partners Generic Partners Generic Partners Generic Partners Generic Partners

Restricted
Initiation

All of the following:

1 Patient has ADHD (Attention Deficit and Hyperactivity Disorder) diagnosed according to DSM-IV or ICD-10 criteria; and

2 Once-daily dosing; and

3 Any of the following:

3.1 Treatment with a subsidised formulation of a stimulant has resulted in the development or worsening of serious adverse reactions or where the combination of subsidised stimulant treatment with another agent would pose an unacceptable medical risk; or

continued...

→ Restriction

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

	Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

continued...

- 3.2 Treatment with a subsidised formulation of a stimulant has resulted in worsening of co-morbid substance abuse or there is a significant risk of diversion with subsidised stimulant therapy; or
 - 3.3 An effective dose of a subsidised formulation of a stimulant has been trialled and has been discontinued because of inadequate clinical response; or
 - 3.4 Treatment with a subsidised formulation of a stimulant is considered inappropriate because the patient has a history of psychoses or has a first-degree relative with schizophrenia; and
 - 4 The patient will not be receiving treatment with atomoxetine in combination with a subsidised formulation of a stimulant, except for the purposes of transitioning from subsidised stimulant therapy to atomoxetine.
- Note: A “subsidised formulation of a stimulant” refers to currently listed methylphenidate hydrochloride tablet formulations (immediate-release, sustained-release and extended-release) or dexamphetamine sulphate tablets.
Note – Strattera cap 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg to be delisted 1 September 2020.

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

131	METHOTREXATE (addition of HSS) Inj 100 mg per ml, 50 ml vial – 1% DV Oct-20 to 2023	79.99	1	Methotrexate Ebewe
181	RITUXIMAB (RIXIMYO) (amended restriction criteria – affected 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

Continuation – indolent, low-grade lymphomas or hairy cell leukaemia*

Re-assessment required after 12 months

Either:

† 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; or

2 Both:

- 2.1 Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy; and
- 2.2 Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m² every 8 weeks (maximum of 12 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.

Initial application – CD20+ low grade or follicular B-cell NHL

Re-assessment required after 9 months

Either:

1 Both:

- 1.1 The patient has CD20+ low grade or follicular B-cell NHL with relapsed disease following prior chemotherapy; and
- 1.2 To be used for a maximum of 6 treatment cycles; or

2 Both:

- 2.1 The patient has CD20+ low grade or follicular B-cell NHL requiring first-line systemic chemotherapy; and
- 2.2 To be used for a maximum of 6 treatment cycles.

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Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

continued...

Renewal – CD20+ low grade or follicular B-cell NHL

Re-assessment required after 24 months

Both:

- 1 Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy; and**
- 2 Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m² every 8 weeks (maximum of 12 cycles).**

200	MYCOPHENOLATE MOFETIL (↑ price)			
	Tab 500 mg	35.90	50	CellCept
	Cap 250 mg	35.90	100	CellCept

RESPIRATORY SYSTEM AND ALLERGIES

202	BUDESONIDE (↓ price and addition of HSS)			
	Nasal spray 50 mcg per dose – 1% DV Oct-20 to 2023	2.54	200 dose	SteroClear
	Nasal spray 100 mcg per dose – 1% DV Oct-20 to 2023	2.84	200 dose	SteroClear
207	NEDOCROMIL (delisting)			
	Aerosol inhaler 2 mg per dose			
	Note – Nedocromil aerosol inhaler 2 mg per dose to be delisted from 1 February 2021.			
207	SODIUM CROMOGLICATE (delisting)			
	Aerosol inhaler 5 mg per dose			
	Note – Sodium cromoglicate aerosol inhaler 5 mg per dose to be delisted from 1 May 2021.			

SENSORY ORGANS

214	ATROPINE SULPHATE (addition of HSS)			
	Eye drops 1% – 1% DV Oct-20 to 2023	17.36	15 ml	Atropt

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS

225	GLYCEROL (↓ price and addition of HSS)			
	Liq – 1% DV Oct-20 to 2023	3.23	500 ml	healthE Glycerol BP Liquid

→ Restriction

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	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

SPECIAL FOODS

235	AMINO ACID FORMULA (amended restriction criteria)			
	→ Powder 1.95 g protein, 8.1 g carbohydrate and 3.5 g fat per 100 ml, 400 g can			<i>e.g. Neocate</i>
	→ Powder 13 g protein, 49 g carbohydrate and 23 g fat per 100 g, 400 g can			<i>e.g. Neocate SYNEO unflavoured</i>
	→ Powder 13.3 g protein, 56 g carbohydrate and 22 g fat per 100 g, 400 g can			<i>e.g. Neocate Junior Unflavoured</i>
	→ Powder 13.5 g protein, 52 g carbohydrate and 24.5 g fat per 100 g, can.....	53.00	400 g	Neocate Gold (Unflavoured)
	→ Powder 14.8 g protein, 51.4 g carbohydrate and 23 g fat per 100 g, can.....	53.00	400 g	Neocate Junior Vanilla
	→ Powder 15 g protein, 56 g carbohydrate and 20 g fat per 100 g, can.....	43.60	400 g	Alfamino Junior
	→ Powder 2.2 g protein, 7.8 g carbohydrate and 3.4 g fat per 100 ml, can.....	53.00	400 g	Elecare LCP (Unflavoured)
	→ Powder 2.2 g protein, 7.8 g carbohydrate and 3.4 g fat per 100 ml, can.....	53.00	400 g	Elecare (Unflavoured) Elecare (Vanilla)

Restricted
Initiation

Any of the following:

- 1 Extensively hydrolysed formula has been reasonably trialled **for 2-4 weeks** and is inappropriate due to documented severe intolerance or allergy or malabsorption; or
- 2 History of anaphylaxis to cow's milk protein formula or dairy products; or
- 3 Eosinophilic oesophagitis: **or**
- 4 **Ultra-short gut; or**
- 5 **Severe Immune deficiency.**

Note: A reasonable trial is defined as a 2-4 week trial.

Continuation

Both All of the following:

- 1 An assessment as to whether the infant can be transitioned to a cow's milk protein, soy, or extensively hydrolysed infant formula has been undertaken; and
- 2 The outcome of the assessment is that the infant continues to require an amino acid infant formula; **and**
- 3 **Amino acid formula is required for a nutritional deficit.**

VACCINES

242	DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE (amended presentation description and addition of HSS)			
	→ Inj 30 IU diphtheria toxoid with 30IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin haemagglutinin , 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5 ml syringe – 0% DV Oct-20 to 2024	0.00	10	Infanrix IPV

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

242	DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE (amended presentation description and addition of HSS) → Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin haemagglutinin , 8 mcg pertactin, 80 D-antigen units poliomyelitis virus, 10 mcg hepatitis B surface antigen in 0.5 ml syringe (1) and inj 10 mcg haemophilus influenzae type B vaccine vial – 0% DV Oct-20 to 2024	0.00	10	Infanrix-hexa
243	BACILLUS CALMETTE-GUERIN VACCINE (addition of HSS) → Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial Danish strain 1331, live attenuated, vial with diluent – 0% DV Oct-20 to 2024	0.00	10	BCG Vaccine
243	DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE (amended restriction criteria, presentation description and addition of HSS) → Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin haemagglutinin and 2.5 mcg pertactin in 0.5 ml syringe – 0% DV Oct-20 to 2024	0.00	1 10	Boostrix Boostrix
Restricted Initiation Any of the following:				
1 A single dose for pregnant women in the second or third trimester of each pregnancy; 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 65 years old; or				
6 A single dose for vaccination of patients aged 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.				
244	MENINGOCOCCAL (A, C, Y AND W-135) CONJUGATE VACCINE (addition of HSS) → Inj 4 mcg or each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial – 0% DV Oct-20 to 2024	0.00	1	Menactra

→ Restriction

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

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

244	MENINGOCOCCAL C CONJUGATE VACCINE (amended restriction criteria) → Inj 10 mcg in 0.5 ml syringe..... 0.00	1	Neisvac-C
	Restricted Initiation – children under 9 months of age Any of the following: 1 Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or 2 One dose Two doses for close contacts of meningococcal cases; or 3 A maximum of two doses for bone marrow transplant patients; or 4 A maximum of two doses for patients following pre- and post-immunosuppression* . Notes: children under seven years nine months of age require two doses 8 weeks apart; a booster dose three years after the primary series and then five yearly . Refer to the Immunisation Handbook for booster schedules with meningococcal ACWY vaccine. *Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.		
244	PNEUMOCOCCAL (PCV10) CONJUGATE VACCINE (amended restriction criteria and addition of HSS) → Inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml prefilled syringe – 0% DV Oct-20 to 2024 0.00	10	Synflorix
	Restricted Initiation Either: 1 A primary course of four three doses for previously unvaccinated individuals up to the age of 59 months inclusive. or 2 Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV13. Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes		
245	PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE (amended restriction criteria) → Inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5 ml syringe 0.00	1 10	Prevenar 13 Prevenar 13
	Restricted Initiation – High risk children who have received PCV10 <i>Therapy limited to 1 dose</i> One Two doses is are funded for high risk children (over the age of 47 12 months and under 18 years) who have previously received four two doses of the primary course of PCV10 . Initiation – High risk children aged under 5 years <i>Therapy limited to 4 doses</i> Both: 1 Up to an additional four doses (as appropriate) are funded for children aged under 5 years for (re-immunisation; and 2 Any of the following: 2.1 on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or 2.2 with primary immune deficiencies; or 2.3 with HIV infection; or		

continued...

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

continued...

- 2.4 with renal failure, or nephrotic syndrome; or
- 2.5 who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
- 2.6 with cochlear implants or intracranial shunts; or
- 2.7 with cerebrospinal fluid leaks; or
- 2.8 receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
- 2.9 with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
- 2.10 pre term infants, born before 28 weeks gestation; or
- 2.11 with cardiac disease, with cyanosis or failure; or
- 2.12 with diabetes; or
- 2.13 with Down syndrome; or
- 2.14 who are pre- or post-splenectomy, or with functional asplenia.

Initiation – High risk adults and children 5 years and over

Therapy limited to 4 doses

Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients 5 years and over with HIV, for patients pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency.

Initiation – Testing for primary immunodeficiency diseases

For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes

245	PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE (addition of HSS) → Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype) – 0% DV Oct-20 to 2024 0.00	1	Pneumovax 23
246	HEPATITIS A VACCINE (addition of HSS) → Inj 720 ELISA units in 0.5 ml syringe – 0% DV Oct-20 to 2024 0.00 → Inj 1440 ELISA units in 1 ml syringe – 0% DV Oct-20 to 2024 0.00	1 1	Havrix Junior Havrix
248	HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV] (addition of HSS) → Inj 270 mcg in 0.5 ml syringe – 0% DV Oct-20 to 2024 0.00	10	Gardasil 9
250	MEASLES, MUMPS AND RUBELLA VACCINE (addition of HSS) → Injection, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml – 0% DV Oct-20 to 2024 0.00	10	Priorix
250	POLIOMYELITIS VACCINE (addition of HSS) → Inj 80 D-antigen units in 0.5 ml syringe – 0% DV Oct-20 to 2024 0.00	1	IPOL

→ Restriction

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

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 July 2020 (continued)

250	ROTAVIRUS ORAL VACCINE (addition of HSS) → Oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator – 0% DV Oct-20 to 2024	0.00	10	Rotarix
251	VARICELLA VACCINE [CHICKENPOX VACCINE] (new listing and addition of HSS) → Inj 1350 PFU prefilled syringe – 0% DV Oct-20 to 2024	0.00	1 10	Varivax Varivax
251	VARICELLA VACCINE [CHICKENPOX VACCINE] (delisting) → Inj 2000 PFU prefilled syringe plus vial	0.00	1 10	Varilrix Varilrix
Note – Varilix inj 2000 PFU prefilled syringe plus vial, 1 and 10 inj pack to be delisted from 1 October 2020.				
251	TUBERCULIN PPD [MANTOUX] TEST (addition of HSS) Inj 5 TU per 0.1 ml, 1 ml vial – 0% DV Oct-20 to 2024	0.00	1	Tubersol

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 June 2020

ALIMENTARY TRACT AND METABOLISM

11	PANCREATIC ENZYME (new listing) Modified release granules pancreatin 60.12 mg (amylase 3,600 Ph Eur U, lipase 5,000 Ph Eur U, protease 200 Ph Eur U).....	34.93	20 g	Creon Micro
17	CALCIUM CARBONATE (new listing) Tab eff 1.25 g (500 mg elemental)			

BLOOD AND BLOOD FORMING ORGANS

32	EPTIFIBATIDE (amended restriction criteria) → Inj 2 mg per ml, 10 ml vial – 1% DV Nov-18 to 2021	138.75	1	Integrilin
	→ Inj 750 mcg per ml, 100 ml vial – 1% DV Nov-18 to 2021	405.00	1	Integrilin
	Restricted Initiation Either Any of the following: 1 For use in patients with acute coronary syndromes undergoing percutaneous coronary intervention; or 2 For use in patients with definite or strongly suspected intra-coronary thrombus on coronary angiography; or 3 For use in patients undergoing intra-cranial intervention.			

DERMATOLOGICALS

54	CETOMACROGOL WITH GLYCEROL (new Pharmacode listing) Crm 90% with glycerol 10%.....	2.35	500 ml	ADE
		3.10	1,000 ml	ADE

Note: DV limit applies to the pack sizes of greater than 100 g.

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 June 2020 (continued)

MUSCULOSKELETAL SYSTEM

99	FEBUXOSTAT (amended restriction)			
	→ Tab 80 mg	39.50	28	Adenuric
	→ Tab 120 mg	39.50	28	Adenuric
	Restricted Initiation Any specialist Both:			
	1 Patient has been diagnosed with gout; and			
	2 Any of the following:			
	2.1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose; or			
	2.2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose; or			
	2.3 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note); or			
	2.4 The patient has previously had an initial Special Authority approval for benzbromarone for treatment of gout.			

Note: In chronic renal insufficiency, particularly when the glomerular filtration rate is 30 ml/minute or less, probenecid may not be effective. The efficacy and safety of febuxostat have not been fully evaluated in patients with severe renal impairment (creatinine clearance less than 30 ml/minute). No dosage adjustment of febuxostat is necessary in patients with mild or moderate renal impairment. Optimal treatment with allopurinol in patients with renal impairment is defined as treatment to the creatinine clearance-adjusted dose of allopurinol then, if serum urate remains greater than 0.36 mmol/l, a gradual increase of the dose of allopurinol to 600 mg or the maximum tolerated dose.

NERVOUS SYSTEM

109	MORPHINE SULPHATE (delisting)			
	Tab long-acting 10 mg	1.93	10	Arrow-Morphine LA
	Note – Arrow-Morphine LA tab long-acting 10 mg to be delisted from 1 October 2020.			
111	FLUOXETINE HYDROCHLORIDE (new listing)			
	Tab dispersible 20 mg, scored	1.98	30	Fluox
	Cap 20 mg	2.91	84	Fluox

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 June 2020 (continued)

124	MODAFINIL (amended restriction criteria) → Tab 100 mg	64.00	60	Modavigil
	Restricted Initiation – Narcolepsy Neurologist or respiratory specialist <i>Re-assessment required after 24 months</i> 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			
	2.3 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 trialed and discontinued because of intolerable side effects; or			
	3.2 Methylphenidate and dexamphetamine are contraindicated.			
	Continuation – Narcolepsy Neurologist or respiratory specialist <i>Re-assessment required after 24 months</i> The treatment remains appropriate and the patient is benefiting from treatment.			

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

131	GEMCITABINE (addition of HSS) Inj 10 mg per ml, 100 ml vial – 1% DV Jul-20 to 2023	15.89	1	Gemcitabine Ebewe
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	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 May 2020

ALIMENTARY TRACT AND METABOLISM

13	ALGLUCOSIDASE ALFA (amended restriction criteria) → Inj 50 mg vial.....	1,142.60	1	Myozyme
	Restricted Initiation Metabolic physician <i>Re-assessment required after 12 months</i> All of the following:			
	1 The patient is aged up to 24 months at the time of initial application and has been diagnosed with infantile Pompe disease; and			
	2 Any of the following:			
	2.1 Diagnosis confirmed by documented deficiency of acid alpha-glucosidase by prenatal diagnosis using chorionic villus biopsies and/or cultured amniotic cells; or			
	2.2 Documented deficiency of acid alpha-glucosidase, and urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides; or			
	2.3 Documented deficiency of acid alpha-glucosidase, and documented molecular genetic testing indicating a disease-causing mutation in the acid alpha-glucosidase gene (GAA gene); or			
	2.4 Documented urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides, and molecular genetic testing indicating a disease-causing mutation in the GAA gene; and			
	3 Patient has not required long-term invasive ventilation for respiratory failure prior to starting enzyme replacement therapy (ERT); and			
	4 Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by ERT or might be reasonably expected to compromise a response to ERT; and			
	5 Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks.			
	Continuation Metabolic physician <i>Re-assessment required after 12 months</i> 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 pre-medication 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.			

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 May 2020 (continued)

14	BETAINE (amended restriction criteria) ➔ Powder for oral soln.....	575.00	180 g	Cystadane
	Restricted Initiation Metabolic physician <i>Re-assessment required after 12 months</i> All of the following: 1 The patient has a confirmed diagnosis of homocystinuria; and 2 Any of the following: 2.1 A cystathionine beta-synthase (CBS) deficiency; or 2.2 A 5,10-methylene-tetrahydrofolate reductase (MTHFR) deficiency; or 2.3 A disorder of intracellular cobalamin metabolism; and 3 An appropriate homocysteine level has not been achieved despite a sufficient trial of appropriate vitamin supplementation.			
	Continuation Metabolic physician <i>Re-assessment required after 12 months</i> The treatment remains appropriate and the patient is benefiting from treatment.			
15	GALSULFASE (amended restriction criteria) ➔ Inj 1 mg per ml, 5 ml vial.....	2,234.00	1	Naglazyme
	Restricted Initiation Metabolic physician <i>Re-assessment required after 12 months</i> Both: 1 The patient has been diagnosed with mucopolysaccharidosis VI; and 2 Either: 2.1 Diagnosis confirmed by demonstration of N-acetyl-galactosamine-4-sulfatase (arylsulfatase B) deficiency confirmed by either enzyme activity assay in leukocytes or skin fibroblasts; or 2.2 Detection of two disease causing mutations and patient has a sibling who is known to have mucopolysaccharidosis VI.			
	Continuation Metabolic physician <i>Re-assessment required after 12 months</i> 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 pre-medication 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	LEVOCARNITINE (new listing) ➔ Oral soln 1,100 mg per 15 ml			

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 May 2020 (continued)

16	SAPROPTERIN DIHYDROCHLORIDE (amended restriction criteria) → Tab soluble 100 mg	1,452.70	30	Kuvan
	Restricted			
	Initiation			
	Metabolic physician			
	<i>Re-assessment required after 1 month</i>			
	All of the following:			
	1 Patient has phenylketonuria (PKU) and is pregnant or actively planning to become pregnant; and			
	2 Treatment with sapropterin is required to support management of 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.			
	Continuation			
	Metabolic physician or any relevant practitioner on the recommendation of a metabolic physician			
	<i>Re-assessment required after 12 months</i>			
	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) → Grans 483 mg per g	1,920.00	174 g	Pheburane
	Restricted			
	Initiation			
	Metabolic physician			
	<i>Re-assessment required after 12 months</i>			
	For the chronic management of a urea cycle disorder involving a deficiency of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.			
	Continuation			
	Metabolic physician			
	<i>Re-assessment required after 12 months</i>			
	The treatment remains appropriate and the patient is benefiting from treatment.			

		Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 May 2020 (continued)

19	CHLORHEXIDINE GLUCONATE (delisting) Mouthwash 0.2%	2.57	200 ml	healthE
Note – healthE mouthwash 0.2%, 200 ml to be delisted from 1 November 2020.				

CARDIOVASCULAR SYSTEM

47	PHENYLEPHRINE HYDROCHLORIDE (↑ price) Inj 10 mg per ml, 1 ml ampoule	142.07	25	Neosynephrine HCL
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DERMATOLOGICALS

55	HYDROCORTISONE ACETATE (delisting) Crm 1%.....	2.48	14.2 g	AFT
Note – AFT crm 1%, 14.2 g to be delisted from 1 November 2020.				

GENITO-URINARY SYSTEM

58	CHLORHEXIDINE GLUCONATE (delisting) Crm 1%..... Lotn 1%, 200 ml.....	1.21 2.98	50 g 1	healthE healthE
Note – healthE crm 1%, 50 g and lotn 1%, 200 ml to be delisted from 1 November 2020.				
59	DINOPROSTONE (↑ price) Vaginal gel 1 mg in 3 g..... Vaginal gel 2 mg in 3 g.....	56.86 69.77	1 1	Prostin E2 Prostin E2
59	OXYTOCIN (Pharmacode change) Inj 10 iu per ml, 1 ml ampoule – 1% DV Nov-18 to 2021	4.98	5	Oxytocin BNM
Note – this is a new Pharmacode listing, 2577046. Pharmacode 2448203 to be delisted from 1 November 2020.				

INFECTIONS

72	TOBRAMYCIN (Pharmacode change) → Solution for inhalation 60 mg per ml, 5 ml	2,200.00	56 dose	TOBI
Note – this is a new Pharmacode listing, 2578891. Pharmacode 2465957 to be delisted 1 August 2020.				
83	RIFABUTIN (↑ price) → Cap 150 mg.....	299.75	30	Mycobutin

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 May 2020 (continued)

MUSCULOSKELETAL SYSTEM

94	HYDROXYCHLOROQUINE (amended restriction criteria) → Tab 200 mg – 1% DV Sep-18 to 2021	7.98	100	Plaquenil
	Restricted Initiation Any of the following: 1 Rheumatoid arthritis; or 2 Systemic or discoid lupus erythematosus; or 3 Malaria treatment or suppression; or 4 Relevant dermatological conditions (cutaneous forms of lupus and lichen planus, cutaneous vasculitides and mucosal ulceration)			
100	DANTROLENE (↑ price) Cap 25 mg	97.50	100	Dantrium
	Inj 20 mg vial	888.00	6	Dantrium IV

NERVOUS SYSTEM

105	BUPIVACAINE HYDROCHLORIDE (↓ price and addition of HSS) Inj 2.5 mg per ml, 20 ml ampoule sterile pack – 1% DV Aug-20 to 2023	23.36	5	Marcain
	Inj 5 mg per ml, 10 ml ampoule sterile pack – 1% DV Aug-20 to 2023	16.20	5	Marcain
	Inj 5 mg per ml, 20 ml ampoule sterile pack – 1% DV Aug-20 to 2023	16.56	5	Marcain
112	DIAZEPAM (↑ price) Rectal tubes 5 mg	43.50	5	Stesolid
115	ERGOTAMINE TARTRATE WITH CAFFEINE (delisted) Tab 1 mg with caffeine 100 mg Note – ergotamine tartrate with caffeine tab 1 mg with caffeine 100 mg delisted 1 May 2020			

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

129	DAUNORUBICIN (↑ price) Inj 2 mg per ml, 10 ml vial	149.50	1	Pfizer
130	MITOMYCIN C (↑ price) Inj 5 mg vial	851.37	1	Arrow
133	DACARBAZINE (↑ price) Inj 200 mg vial	62.70	1	DBL Dacarbazine
143	CALCIUM FOLINATE (↑ price) Tab 15 mg	114.69	10	DBL Leucovorin Calcium

		Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 May 2020 (continued)

144	VINCRIStINE SULPHATE (↑ price) Inj 1 mg per ml, 2 ml vial	102.73	5	DBL Vincristine Sulfate
147	ETANERCEPT (↓ price) → 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

RESPIRATORY SYSTEM AND ALLERGIES

202	PROMETHAZINE HYDROCHLORIDE (↑ price) Inj 25 mg per ml, 2 ml ampoule	17.87	5	Hospira
203	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			
	<i>Re-assessment required after 12 months</i>			
	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 Note); 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			
	<i>Re-assessment required after 12 months</i>			
	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.			

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 May 2020 (continued)

204	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			
	<i>Re-assessment required after 12 months</i>			
	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			
	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			
	<i>Re-assessment required after 12 months</i>			
	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.			
205	TERBUTALINE SULPHATE (new listing)			
	Powder for inhalation, 200 mcg per dose (equivalent to 250 mcg metered dose), breath activated	22.20	120 dose	Bricanyl Turbuhaler

SENSORY ORGANS

211	OLOPATADINE (brand change)			
	Eye drops 0.1% – 1% DV Oct-20 to 2022	2.20	5 ml	Olopatadine Teva
	Note – Patanol eye drops 0.1% to be delisted from 1 October 2020.			

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 May 2020 (continued)

VARIOUS

218	CHLORHEXIDINE (delisting) Soln 4%	1.86	50 ml	healthE
	Note – healthE soln 4%, 50 ml to be delisted from 1 November 2020.			
218	IODINE WITH ETHANOL (delisting) Soln 1% with ethanol 70%, 100 ml.....	9.30	1	healthE
	Note – healthE soln 1% with ethanol 70%, 100 ml to be delisted from 1 November 2020			
218	CHLORHEXIDINE WITH ETHANOL (delisting) Soln 0.5% with ethanol 70%, non-staining (pink) 100 ml.....	2.65	1	healthE
	Soln 2% with ethanol 70%, non-staining (pink) 100 ml.....	3.54	1	healthE
	Soln 0.5% with ethanol 70%, staining (red) 100 ml.....	2.90	1	healthE
	Soln 2% with ethanol 70%, staining (red) 100 ml	3.86	1	healthE
	Soln 0.5% with ethanol 70%, non-staining (pink) 500 ml.....	5.45	1	healthE
	Soln 0.5% with ethanol 70%, staining (red) 500 ml	5.90	1	healthE
	Soln 2% with ethanol 70%, staining (red) 500 ml	9.56	1	healthE
	Note – healthE soln 0.5% with ethanol 70%, non staining (pink) and staining (red), 100 ml & 500 ml; soln 2% with ethanol 70%, non staining (pink), 100 ml and staining (red), 100 ml & 500 ml to be delisted from 1 November 2020.			
218	POVIDONE-IODINE (pack size change) Oint 10% – 1 DV Oct-20 to 2023	7.40	65 g	Betadine
	Note – Betadone oint 10%, 25 g to be delisted from 1 October 2020.			

SPECIAL FOODS

240	ENTERAL FEED 1 KCAL/ML (new listing) Liquid 4 g protein, 12.3 g carbohydrate and 3.9 g fat per 100 ml, 1,000 ml bottle			<i>e.g. Nutrison Low Sodium</i>
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	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020

ALIMENTARY TRACT AND METABOLISM

6	MESALAZINE (↓ price and addition of HSS) Tab long-acting 500 mg – 1% DV Jul-20 to 2023	56.10	100	Pentasa
7	HYOSCINE BUTYLBROMIDE (↓ price and addition of HSS) Inj 20 mg, 1 ml ampoule – 1% DV Jul-20 to 2023	6.35	5	Buscopan
7	MEBEVERINE HYDROCHLORIDE (↓ price and addition of HSS) Tab 135 mg – 1% DV Jul-20 to 2023	9.20	90	Colofac
9	GLUCAGON HYDROCHLORIDE (addition of HSS) Inj 1 mg syringe kit – 1% DV Jul-20 to 2023	32.00	1	Glucagen Hypokit

BLOOD AND BLOOD FORMING ORGANS

31	ENOXAPARIN SODIUM (Pharmacode change)			
	Inj 20 mg in 0.2 ml syringe.....	27.93	10	Clexane
	Inj 40 mg in 0.4 ml syringe.....	37.27	10	Clexane
	Inj 60 mg in 0.6 ml syringe.....	56.18	10	Clexane
	Inj 80 mg in 0.8 ml syringe.....	74.90	10	Clexane
	Inj 100 mg in 1 ml syringe.....	93.80	10	Clexane
	Inj 120 mg in 0.8 ml syringe.....	116.55	10	Clexane Forte
	Inj 150 mg in 1 ml syringe.....	133.20	10	Clexane Forte

Note – these are new Pharmacode listings, current Pharmacodes: 795615, 795623, 416991, 417009, 417017, 389366 and 389390 to be delisted from 1 January 2021.

31	HEPARIN SODIUM (↑ price)			
	Inj 1,000 iu per ml, 1 ml ampoule	197.06	50	Hospira
	Inj 5,000 iu per ml, 1 ml ampoule	32.66	5	Hospira
31	HEPARINISED SALINE (↑ price)			
	Inj 10 iu per ml, 5 ml ampoule	65.48	50	Pfizer
31	WARFARIN SODIUM (↓ price)			
	Tab 1 mg	6.46	100	Marevan
	Tab 3 mg	10.03	100	Marevan
	Tab 5 mg	11.48	100	Marevan
34	PEGFILGRASTIM (amended restriction criteria)			
	➔ Inj 6 mg per 0.6 ml syringe	1,080.00	1	Neulastim
	Restricted Initiation For prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 5 20%*).			
	Note: *Febrile neutropenia risk greater than or equal to 5 20% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines			

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

CARDIOVASCULAR SYSTEM

39	SACUBITRIL WITH VALSARTAN (amended restriction criteria)			
	→ Tab 24.3 mg with valsartan 25.7 mg	190.00	56	Entresto 24/26
	→ Tab 48.6 mg with valsartan 51.4 mg	190.00	56	Entresto 49/51
	→ Tab 97.2 mg with valsartan 102.8 mg	190.00	56	Entresto 97/103

Restricted

Initiation

Re-assessment required after 12 months

All of the following:

- 1 Patient has heart failure; and
- 2 Any of the following:
 - 2.1 Patient is in NYHA/WHO functional class II; or
 - 2.2 Patient is in NYHA/WHO functional class III; or
 - 2.3 Patient is in NYHA/WHO functional class IV; and

3 Either:

- 3.1 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; or
- 3.2 **An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment; and**

4 Patient is receiving concomitant optimal standard chronic heart failure treatments.

Continuation

Re-assessment required after 12 months

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

Note: Due to the angiotensin II receptor blocking activity of sacubitril with valsartan it should not be co-administered with an ACE inhibitor or another ARB.

41	LABETALOL (brand change)			
	Tab 100 mg – 1% DV Sep-20 to 2024	14.50	100	Trandate
	Tab 200 mg – 1% DV Sep-20 to 2024	27.00	100	Trandate

Note – Presolol tab 100 mg and 200 mg to be delisted from 1 September 2020.

41	LABETALOL (new listing)			
	Tab 50 mg			

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

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

49	SILDENAFIL (amended restriction criteria – affected criteria shown only)		
	→ Tab 25 mg – 1% DV Sep-18 to 2021	0.64	4
	→ Tab 50 mg – 1% DV Sep-18 to 2021	0.64	4
	→ Tab 100 mg – 1% DV Sep-18 to 2021	6.60	12
	→ 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.		

DERMATOLOGICALS

55	HYDROCORTISONE (brand change)		
	Crn 1%, 100 g – 1% DV Sep-20 to 2022	3.70	100 g
	Note – DermAssist crn 1%, 30 g to be delisted from 1 September 2020.		
56	BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL (new listing)		
	Foam spray 500 mcg with calcipotriol 50 mcg per g	59.95	60 g
			Enstilar

HORMONE PREPARATIONS

66	OESTRIOL (new listing and addition of HSS)		
	Tab 2 mg – 1% DV Sep-20 to 2023	7.00	30
			Ovestin

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

INFECTIONS

74	CEFTAROLINE FOSAMIL († price) → Inj 600 mg vial	1,595.00	10	Zinforo
76	PIPERACILLIN WITH TAZOBACTAM (new listing) → Inj 4 g with tazobactam 0.5 g vial	38.00	10	PiperTaz Sandoz
78	TETRACYCLINE (new listing) Tab 250 mg	21.42	28	Accord
78	TETRACYCLINE (delisting) Cap 500 mg	46.00	30	Tetracyclin Wolff
	Note – Tetracyclin Wolff cap 500 mg to be delisted from 1 December 2020.			
84	METRONIDAZOLE (delisting) Tab 200 mg	10.45	100	Trichozole
	Tab 400 mg	18.15	100	Trichozole
	Note – Trichozole tab 200 mg and 400 mg to be delisted from 1 September 2020.			
84	PRIMAQUINE PHOSPHATE (amended chemical name) → Tab 7.5 mg → Tab 15 mg			
90	EMTRICITABINE WITH TENOFOVIR DISOPROXIL (amended restriction criteria) → Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) – 1% DV Jun-19 to 2022	61.15	30	Teva

Restricted

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

continued...

→ Restriction

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

	Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

continued...

- 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.

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.

NERVOUS SYSTEM

112	DIAZEPAM († price) Inj 5 mg per ml, 2 ml ampoule	23.66	5	Hospira
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Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

114 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.

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.

115 SUMATRIPTAN (brand change)

Inj 12 mg per ml, 0.5 ml prefilled pen

– 1% DV Sep-20 to 2022 34.00 2 **Imigran**

Note – Clustran inj 12 mg per ml, 0.5 ml prefilled pen to be delisted from 1 September 2020.

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130	MITOMYCIN C (amended brand name) Inj 5 mg vial	204.08	1	Arrow Teva
131	GEMCITABINE (addition of HSS) Inj 10 mg per ml, 100 ml vial – 1% DV Jul-20 to 2023	15.89	1	Gemcitabine Ebewe
133	LLENALIDOMIDE (new listing) → Cap 5 mg..... → Cap 10 mg..... → Cap 15 mg.....	5,122.76 6,207.00 7,239.18	28 28 28	Revlimid Revlimid Revlimid
133	LLENALIDOMIDE (amended restriction criteria) → Cap 10 mg (↓ price)..... → Cap 15 mg (↓ price)..... → Cap 25 mg.....	4,655.25 5,429.39 7,627.00	21 21 21	Revlimid Revlimid Revlimid

Initiation – (Relapsed/refractory disease)

Haematologist

Re-assessment required after 6 months

All of the following:

1 Patient has relapsed or refractory multiple myeloma with progressive disease; and

2 **Patient has not previously been treated with lenalidomide**; and

3 ²Either

3.1 ~~2-1~~ Lenalidomide to be used as third line* treatment for multiple myeloma; or

3.2 ~~2-2~~ Both:

3.2.1 ~~2-2-1~~ Lenalidomide to be used as second line treatment for multiple myeloma; and

3.2.2 ~~2-2-2~~ The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and

4 ³Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

Continuation - (Relapsed/refractory disease)

Haematologist

Re-assessment required after 6 months

Both:

1 No evidence of disease progression; and

2 The treatment remains appropriate and patient is benefitting from treatment.

Initiation - (Maintenance following first-line autologous stem cell transplant (SCT))

Haematologist

Reassessment required after 6 months

All of the following:

1 **Patient has newly diagnosed symptomatic multiple myeloma and has undergone first-line treatment that included an autologous stem cell transplantation; and**

2 **Patient has at least a stable disease response in the first 100 days after transplantation; and**

3 **Lenalidomide maintenance is to be commenced within 6 months of transplantation; and**

4 **The patient has ECOG performance score of 0-1; and**

5 **Lenalidomide to be administered at a maximum dose of 15 mg/day.**

continued...

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

continued...

Continuation – (Maintenance following first line autologous SCT)

Haematologist

Reassessment required after 6 months

Both:

1 No evidence of disease progression; and

2 The treatment remains appropriate and patient is benefitting from treatment.

Note: Indication marked with * is an unapproved indication. A line of treatment is considered to comprise either: a) a known therapeutic chemotherapy regimen and supportive treatments or b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments. Prescriptions must be written by a registered prescriber in the lenalidomide risk management programme operated by the supplier.

138	ERLOTINIB (amended restriction criteria – new criteria shown only)			
	→ Tab 100 mg	764.00	30	Tarceva
	→ Tab 150 mg	1,146.00	30	Tarceva

Restricted

Continuation – pandemic circumstances

Re-assessment required after 6 months

All of the following:

1 The patient is clinically benefitting 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.

139	GEFITINIB (amended restriction criteria – new criteria shown only)			
	→ Tab 250 mg	1,700.00	30	Iressa

Restricted

Continuation – pandemic circumstances

Re-assessment required after 6 months

All of the following:

1 The patient is clinically benefitting 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.

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

140	PALBOCICLIB (new listing)			
	→ Cap 75 mg.....	4,000.00	21	Ibrance
	→ Cap 100 mg.....	4,000.00	21	Ibrance
	→ Cap 125 mg.....	4,000.00	21	Ibrance
	Initiation			
	Medical oncologist			
	<i>Reassessment required after 6 months</i>			
	All of the following:			
	1 Patient has unresectable locally advanced or metastatic breast cancer; and			
	2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and			
	3 Patient has an ECOG performance score of 0-2; and			
	4 Either:			
	second or subsequent line setting			
	4.1 Disease has relapsed or progressed during prior endocrine therapy; or			
	4.2 Both:			
	first line setting			
	4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and			
	4.2.2 Either:			
	4.2.2.1 Patient has not received prior systemic endocrine treatment for metastatic disease; or			
	4.2.2.2 All of the following:			
	4.2.2.2.1 Patient commenced treatment with palbociclib in combination with an endocrine agent prior to 1 April 2020; and			
	4.2.2.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease; and			
	4.2.2.2.3 There is no evidence of progressive disease; and			
	5 Treatment must be used in combination with an endocrine partner.			
	Continuation			
	Medical oncologist			
	<i>Reassessment required after 12 months</i>			
	All of the following:			
	1 Treatment must be used in combination with an endocrine partner; and			
	2 No evidence of progressive disease; and			
	3 The treatment remains appropriate and the patient is benefitting from treatment.			
142	SUNITINIB (amended restriction criteria – new 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
	Restricted			
	Continuation – GIST pandemic circumstances			
	<i>Re-assessment required after 6 months</i>			
	All of the following:			
	1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and			
	2 The patient is clinically benefitting 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.			

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

144	ABIRATERONE ACETATE (amended restriction criteria) → Tab 250 mg.....	4,276.19	120	Zytiga
	Restricted Initiation Medical oncologist, radiation oncologist or urologist <i>Re-assessment required after 6 months</i> All of the following: 1 Patient has prostate cancer; and 2 Patient has metastases; and 3 Patient's disease is castration resistant; and 4 Either: 4.1 All of the following: 4.1.1 Patient is symptomatic; and 4.1.2 Patient has disease progression (rising serum PSA) after second line anti-androgen therapy; and 4.1.3 Patient has ECOG performance score of 0-1; and 4.1.4 Patient has not had prior treatment with taxane chemotherapy; or 4.2 All of the following: 4.2.1 Patient's disease has progressed following prior chemotherapy containing a taxane; and 4.2.2 Patient has ECOG performance score of 0-2; and 4.2.3 Patient has not had prior treatment with abiraterone.			
	Continuation Medical oncologist, radiation oncologist or urologist <i>Re-assessment required after 6 months</i> All of the following: 1 Significant decrease in serum PSA from baseline; and 2 No evidence of clinical disease progression; and 3 No initiation of taxane chemotherapy with abiraterone; and 4 The treatment remains appropriate and the patient is benefiting from treatment.			
144	VINBLASTINE SULPHATE (↑ price) Inj 1 mg per ml, 10 ml vial.....	270.37	5	Hospira
145	FULVESTRANT (new listing) → Inj 50 mg per ml, 5 ml prefilled syringe.....	1,068.00	2	Faslodex
	Initiation Medical Oncologist <i>Re-assessment required after 6 months</i> All of the following: 1 Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and 2 Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease; and 3 Treatment to be given at a dose of 500 mg monthly following loading doses; and 4 Treatment to be discontinued at disease progression.			
	Continuation Medical Oncologist <i>Re-assessment required after 6 months</i> All of the following: 1 Treatment remains appropriate and patient is benefitting from treatment; and 2 Treatment to be given at a dose of 500 mg monthly; and 3 No evidence of disease progression.			

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

145	OCTREOTIDE (amended restriction criteria – new 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.			
154	ABCIXIMAB (delisting)			
	→ Inj 2 mg per ml, 5 ml vial.....	579.53	1	ReoPro
	Note – ReoPro inj 2 mg per ml, 5 ml vial to be delisted from 1 January 2021.			
172	MEPOLIZUMAB (new listing)			
	→ Inj 100 mg vial.....	1,638.00	1	Nucala
	Restricted			
	Initiation – (Severe eosinophilic asthma)			
	Respiratory physician or clinical immunologist			
	Re-assessment required after 12 months			
	All of the following			
	1 Patient must be aged 12 years or older; and			
	2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and			
	3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and			
	4 Patient has a blood eosinophil count of greater than 0.5×10^9 cells/L in the last 12 months; and			
	5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long acting beta-2 agonist, or budesonide/formoterol as part of the single maintenance and reliever therapy regimen, unless contraindicated or not tolerated; and			
	6 Either:			
	6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or			
	6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and			
	7 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment.			
	Continuation – (Severe eosinophilic asthma)			
	Respiratory physician or clinical immunologist			
	Re-assessment required after 2 years			
	Both:			
	1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and			
	2 Either:			
	2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with mepolizumab; or			
	2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.			

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

175	RITUXIMAB (MABTHERA) (amended restriction criteria – affected criteria shown only)		
	→ 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		
	Continuation – severe cold haemagglutinin disease (CHAD)		
	Haematologist		
	<i>Re-assessment required after 4 8 weeks</i>		
	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/m ² 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.		
	Continuation – warm autoimmune haemolytic anaemia (warm AIHA)		
	Haematologist		
	<i>Re-assessment required after 4 8 weeks</i>		
	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/m ² 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.		
	Continuation – immune thrombocytopenic purpura (ITP)		
	Haematologist		
	<i>Re-assessment required after 4 8 weeks</i>		
	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/m ² 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.		
	Continuation – thrombotic thrombocytopenic purpura (TTP)		
	Haematologist		
	<i>Re-assessment required after 4 8 weeks</i>		
	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.		

continued...

Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

continued...

Continuation – ANCA associated vasculitis

Re-assessment required after-4 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.

Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)

Nephrologist

Re-assessment required after-4 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/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

Continuation – Steroid resistant nephrotic syndrome (SRNS)

Nephrologist

Re-assessment required after-4 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/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

181 RITUXIMAB (RIXIMYO) (amended restriction criteria – affected 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 – severe cold haemagglutinin disease (CHAD)

Haematologist

Re-assessment required after 4-8 weeks

All of the following Both:

- 1 Patient has cold haemagglutinin disease*; and
- 2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms; **and**
- 3 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.

Continuation – severe cold haemagglutinin disease (CHAD)

Haematologist

Re-assessment required after 4-8 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)

Haematologist

Re-assessment required after 4-8 weeks

All of the following Both:

- 1 Patient has warm autoimmune haemolytic anaemia*; and
- 2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin; **and**
- 3 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.

Continuation – warm autoimmune haemolytic anaemia (warm AIHA)

Haematologist

Re-assessment required after 4-8 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.

continued...

→ Restriction

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

Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

continued...

Initiation – immune thrombocytopenic purpura (ITP)

Haematologist

Re-assessment required after-4 8 weeks

All of the following Both:

1 Either:

- 1.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
- 1.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and

2 Any of the following:

- 2.1 Treatment with steroids and splenectomy have been ineffective; or
- 2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
- 2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy); **and**

3 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.

Continuation – immune thrombocytopenic purpura (ITP)

Haematologist

Re-assessment required after-4 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)

Haematologist

Re-assessment required after-4 8 weeks

Both:

1 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; and

2 Either:

- 2.1 Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or
- 2.2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology.

Note: Indications marked with * are unapproved indications.

Continuation – thrombotic thrombocytopenic purpura (TTP)

Haematologist

Re-assessment required after-4 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.

continued...

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

continued...

Initiation – ANCA associated vasculitis

Re-assessment required after 4 8 weeks

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis*; and
- 2 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; and
- 3 Any of the following:
 - 3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
 - 3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g; or
 - 3.3 Cyclophosphamide and methotrexate are contraindicated; or
 - 3.4 Patient is a female of child-bearing potential; or
 - 3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note: Indications marked with * are unapproved indications.

Continuation – ANCA associated vasculitis

Re-assessment required after 4 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 – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)

Nephrologist

Re-assessment required after 4 8 weeks

All of the following:

- 1 Patient is a child with SDNS* or FRNS*; and
- 2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
- 3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
- 4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
- 5 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 a * are unapproved indications.

Continuation – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)

Nephrologist

Re-assessment required after 4 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/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

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	Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

continued...

Initiation – Steroid resistant nephrotic syndrome (SRNS)

Nephrologist

Re-assessment required after-4 8 weeks

All of the following:

- 1 Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and
- 2 Treatment with tacrolimus for at least 3 months has been ineffective; and
- 3 Genetic causes of nephrotic syndrome have been excluded; 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 a * are unapproved indications.

Continuation – Steroid resistant nephrotic syndrome (SRNS)

Nephrologist

Re-assessment required after-4 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/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with a * are unapproved indications.

197 NIVOLUMAB (amended restriction criteria)

→ 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

Restricted

Initiation

Medical oncologist

Re-assessment required after 4 months

All of the following:

- 1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 2 Patient has measurable disease as defined by RECIST version 1.1; and
- 3 The patient has ECOG performance score of 0-2; and
- 4 Either:
 - 4.1 Patient has not received funded pembrolizumab; or
 - 4.2 Both:
 - 4.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
 - 4.2.2 The cancer did not progress while the patient was on pembrolizumab; and
- 5 ~~Nivolumab is to be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks; and~~
- 6 ~~Baseline measurement of overall tumour burden is documented (see Note); and~~
- 7 ~~Documentation confirming that the patient has been informed and acknowledges that the initial-funded treatment period of with nivolumab will not be continued beyond 12 weeks (6 cycles) if their disease progresses during this time.~~

Continuation

Medical oncologist

Re-assessment required after 4 months

Either:

- 1 All of the following:
 - 1.1 Any of the following:

continued...

Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

continued...

- 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; ~~and or~~
- ~~1.5 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks; 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; ~~and~~
 - ~~2.4 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks.~~

Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47).

Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Measurable disease includes by CT or MRI imaging or caliper measurement by clinical exam. Target lesion measurements should be assessed using the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks.

Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

	Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

198	PEMBROLIZUMAB (amended restriction criteria) → Inj 25 mg per ml, 4 ml vial.....	4,680.00	1	Keytruda
	Restricted Initiation Medical oncologist <i>Re-assessment required after 4 months</i> All of the following: 1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and 2 Patient has measurable disease as defined by RECIST version 1.1; and 3 The patient has ECOG performance score of 0-2; and 4 Either: 4.1 Patient has not received funded nivolumab; or 4.2 Both: 4.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and 4.2.2 The cancer did not progress while the patient was on nivolumab; and 5 Pembrolizumab is to be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks; and 6 Baseline measurement of overall tumour burden is documented (see Note); and 7 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of with pembrolizumab will not be continued beyond 12 weeks (4 cycles) if their disease progresses during this time.			
	Continuation Medical oncologist <i>Re-assessment required after 4 months</i> 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; and or 1.5 Pembrolizumab will be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks; 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; and 2.4 Pembrolizumab will be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks.			

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Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

continued...

Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Measurable disease includes by CT or MRI imaging or caliper measurement by clinical exam. Target lesion measurements should be assessed using the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks.

Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

200	EVEROLIMUS (amended restriction criteria – new criteria shown only)			
	→ Tab 5 mg.....	4,555.76	30	Afinitor
	→ Tab 10 mg.....	6,512.29	30	Afinitor

Restricted

Continuation – pandemic circumstances

Re-assessment required after 6 months

All of the following:

- 1 The patient is clinically benefitting 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.

RESPIRATORY SYSTEM AND ALLERGIES

205	PHOLCODINE (Pharmacode change)			
	Oral liq 1 mg per ml – 1% DV Jun-20 to 2022	3.09	200 ml	AFT Pholcodine Linctus BP

Note – this is a new Pharmacode listing 2586932. 2142252 to be delisted from 1 September 2020.

VARIOUS

218	POVIDONE-IODINE WITH ETHANOL (delisting)			
	Soln 10% with ethanol 30%	10.00	500 ml	Betadine Skin Prep

Note – Betadine Skin Prep soln 10% with ethanol 30% to be delisted from 1 June 2020.

→ Restriction

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

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 April 2020 (continued)

SPECIAL FOODS

238	PAEDIATRIC ORAL FEED 1 KCAL/ML (delisting revoked) → Liquid 4.2 g protein, 16.7 g carbohydrate and 7.5 g fat per 100 ml, bottle.....	1.07	200 ml	Pediasure (Chocolate) Pediasure (Strawberry) Pediasure (Vanilla)
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Note – Pediasure (Chocolate, Strawberry and Vanilla) Liquid 4.2 g protein, 16.7 g carbohydrate and 7.5 g fat per 100 ml, bottle, 200 ml will no longer be delisted from 1 September 2020.

VACCINES

242	ADULT DIPHTHERIA AND TETANUS VACCINE (delisting) → Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml syringe – 0% DV Jul-17 to 2020	0.00	5	ADT Booster
Note – ADT Booster inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml syringe to be delisted from 1 October 2020.				
247	HEPATITIS B RECOMBINANT VACCINE (delisting) → Inj 5 mcg in 0.5 ml vial – 0% DV Jul-17 to 2020	0.00	1	HBvaxPRO
	→ Inj 10 mcg in 1 ml vial.....	0.00	1	HBvaxPRO
	→ Inj 40 mcg per 1 ml vial – 0% DV Jul-17 to 2020	0.00	1	HBvaxPRO
Note – HBvaxPRO inj 5 mcg in 0.5 ml vial, 10 mcg in 1 ml vial and 40 mcg per 1 ml vial to be delisted from 1 October 2020.				
247	HEPATITIS B RECOMBINANT VACCINE (addition of HSS) → Inj 20 mcg per 1 ml prefilled syringe – 0% DV Oct-20 to 2024	0.00	1	Engerix-B
249	INFLUENZA VACCINE (new listing) → Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)	9.00	1	Influvac Tetra (2020 Formulation)

Effective 13 March 2020

NERVOUS SYSTEM

111	FLUOXETINE HYDROCHLORIDE (↑ price) Tab dispersible 20 mg, scored.....	9.93	30	Arrow-Fluoxetine
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