Pharmaceutical Management Agency New Zealand Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

June 2020

Cumulative for April, May and June 2020



Contents

Summary of decisions effective 1 June 2020	3
Section H changes to Part II	4
Index	. 36

Summary of decisions EFFECTIVE 1 JUNE 2020

- Calcium carbonate tab eff 1.25 g (500 mg elemental) new listing
- Cetomacrogol with glycerol (ADE) crm 90% with glycerol 10%, 500 ml and 1,000 ml new listing
- Eptifibatide (Integrilin) inj 2 mg per ml, 10 ml vial and inj 750 mcg per ml, 100 ml vial amended restriction criteria
- Febuxostat (Adenuric) tab 80 mg and 120 mg amended restriction criteria
- Fluoxetine hydrochloride (Fluox) tab dispersible 20 mg, scored and cap 20 mg
 new listing
- Gemcitabine (Gemcitabine Ebewe) inj 10 mg per ml, 100 ml vial
 addition of HSS
- Modafinil (Modavigil) tab 100 mg amended restriction criteria
- Morphine sulphate (Arrow-Morphine LA) tab long-acting 10 mg
 to be delisted 1 October 2020
- Pancreatic enzyme (Creon Micro) modified release granules pancreatin 60.12 mg (amylase 3,600 Ph Eur U, lipase 5,000 Ph Eur U, protease 200 Ph Eur U), 20 g new listing

Brand or Generic Manufacturer

Section H changes to Part II

Effective 1 June 2020

ALIMENTARY TRACT AND METABOLISM

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)

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)

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

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

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 mg1.93	10	Arrow-Morphine LA
	Note – Arrow-Morphine LA tab long-acting 10 mg to be delisted from 1 Oc	tober 2020.	
111	FLUOXETINE HYDROCHLORIDE (new listing)		
	Tab dispersible 20 mg, scored	30	Fluox
	Cap 20 mg2.91	84	Fluox

Price		Brand or
(ex man. Excl. G	iST)	Generic
 \$	Per	Manufacturer

124 MODAFINIL (amended restriction criteria)

Restricted

Initiation - Narcolepsy

Neurologist or respiratory specialist

Re-assessment required after 24 months

All of the following:

- 1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
- 2 Either Any of the following:
 - 2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eve 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 trialled and discontinued because of intolerable side effects; or
 - 3.2 Methylphenidate and dexamphetamine are contraindicated.

Continuation - Narcolepsy

Neurologist or respiratory specialist

Re-assessment required after 24 months

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 202315.89

1 Gemcitabine Ebewe

Brand or Generic Manufacturer

Changes to Section H Part II - effective 1 May 2020

ALIMENTARY TRACT AND METABOLISM

13 ALGLUCOSIDASE ALFA (amended restriction criteria)

Restricted

Initiation

Metabolic physician

Re-assessment required after 12 months

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

Re-assessment required after 12 months

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

Brand or Generic Manufacturer

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

14 BETAINE (amended restriction criteria)

Restricted

Initiation

Metabolic physician

Re-assessment required after 12 months

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

Re-assessment required after 12 months

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

Re-assessment required after 12 months

Both:

- 1 The patient has been diagnosed with mucopolysaccharidosis VI; and
- 2 Fither
 - 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

Re-assessment required after 12 months

- 1 The treatment remains appropriate for the patient and the patient is benefiting from treatment; and
- 2 Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate premedication and/or adjustment of infusion rates; and
- 3 Patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by Enzyme Replacement Therapy (ERT); and
- 4 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT.
- 16 LEVOCARNITINE (new listing)
 - → Oral soln 1,100 mg per 15 ml

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

16 SAPROPTERIN DIHYDROCHLORIDE (amended restriction criteria)

Restricted

Initiation

Metabolic physician

Re-assessment required after 1 month

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 Re-assessment required after 12 months

All of the following:

- 1 Fither:
 - 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)

Restricted

Initiation

Metabolic physician

Re-assessment required after 12 months

For the chronic management of a urea cycle disorder involving a deficiency of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.

Continuation

Metabolic physician

Re-assessment required after 12 months

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

		Price (ex man. Excl. G \$	ST) Per	Brand or Generic Manufacturer
Chan	ges to Section H Part II – effective 1 May 20	20 (continued)		
19	CHLORHEXIDINE GLUCONATE (delisting) Mouthwash 0.2%		200 ml 2020.	healthE
CARE	DIOVASCULAR SYSTEM			
47	PHENYLEPHRINE HYDROCHLORIDE († price) Inj 10 mg per ml, 1 ml ampoule	142.07	25	Neosynephrine HCL
DERN	NATOLOGICALS			
55	HYDROCORTISONE ACETATE (delisting) Crm 1% Note – AFT crm 1%, 14.2 g to be delisted from 1 November 1		14.2 g	AFT
GENI	TO-URINARY SYSTEM			
58	CHLORHEXIDINE GLUCONATE (delisting) Crm 1% Lotn 1%, 200 ml Note – healthE crm 1%, 50 g and lotn 1%, 200 ml to be of	2.98	50 g 1 vember 2020.	healthE healthE
59	DINOPROSTONE († price) Vaginal gel 1 mg in 3 g Vaginal gel 2 mg in 3 g		1 1	Prostin E2 Prostin E2
59	OXYTOCIN (Pharmacode change) Inj 10 iu per ml, 1 ml ampoule – 1% DV Nov-18 to 20 Note – this is a new Pharmacode listing, 2577046. Pharm		5 to be delisted t	Oxytocin BNM from 1 November 2020.
INFE	CTIONS			
72	TOBRAMYCIN (Pharmacode change) → Solution for inhalation 60 mg per ml, 5 ml Note – this is a new Pharmacode listing, 2578891. Pharmacode listing, 2578891.		56 dose to be delisted	TOBI 1 August 2020.
83	RIFABUTIN († price) → Cap 150 mg	299.75	30	Mycobutin

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

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เพเบอ	6UL	.U3REL	.CIAL	SISIEN	/1

MOOO	OLOGRELLIAL GIGILIN			
94	HYDROXYCHLOROQUINE (amended restriction criteria) → Tab 200 mg – 1% DV Sep-18 to 2021		100 planus, cu	Plaquenil taneous vasculitides
100	DANTROLENE († price) Cap 25 mg		100 6	Dantrium Dantrium IV
NERV	OUS 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 Inj 5 mg per ml, 10 ml ampoule sterile pack - 1% DV Aug-20 to 2023 Inj 5 mg per ml, 20 ml ampoule sterile pack - 1% DV Aug-20 to 2023	16.20	5 5 5	Marcain Marcain 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	0 mg delisted	1 May 202	20
ONCO	LOGY AGENTS AND IMMUNOSUPPRESSANTS			
129	DAUNORUBICIN († price) Inj 2 mg per ml, 10 ml vial1	49.50	1	Pfizer
130	MITOMYCIN C († price) Inj 5 mg vial8	51.37	1	Arrow
133	DACARBAZINE († price) Inj 200 mg vial	62.70	1	DBL Dacarbazine
143	CALCIUM FOLINATE († price) Tab 15 mg1	14.69	10	DBL Leucovorin Calcium

	(e)	Price k man. Excl. GST \$	Γ) Per	Brand or Generic Manufacturer
Chai	nges 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 → Inj 50 mg autoinjector – 5% DV Sep-19 to 2024 → Inj 50 mg syringe – 5% DV Sep-19 to 2024	1,050.00	4 4 4	Enbrel Enbrel Enbrel
RESI	PIRATORY 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		60 60	Ofev Ofev

Initiation – idiopathic pulmonary fibrosis

Respiratory specialist

Re-assessment required after 12 months

All of the following:

- 1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
- 2 Forced vital capacity is between 50% and 90% predicted; and
- 3 Nintedanib is to be discontinued at disease progression (See 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

Re-assessment required after 12 months

All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
- 2 Nintedanib is not to be used in combination with subsidised pirfenidone; and
- 3 Nintedanib is to be discontinued at disease progression (See Note).

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

		Price (ex man. Excl. G \$	SST) Per	Brand or Generic Manufacturer			
Char	nges to Section H Part II – effective 1 Ma	y 2020 (continued)					
204	PIRFENIDONE (amended restriction criteria) → Tab 801 mg	nonary fibrosis by a multipredicted; and gression (See Notes); are h subsidised nintedanib; atment with nintedanib; atment with nintedanib; obut discontinued ninted but the patient's disease in predicted FVC within the interval of the product of the patient is benefitting from a h subsidised nintedanib;	nd and or anib within 1 e has not pro n any 12 mo	12 weeks due to ogressed (disease onth period since starting			
	Note: disease progression is defined as a decline in period.	Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month					
205	TERBUTALINE SULPHATE (new listing) Powder for inhalation, 200 mcg per dose (equivalent to 250 mcg metered dose), breath		120 dose	Bricanyl Turbuhaler			

SENSORY ORGANS

211

OLOPATADINE (brand change)		
Eye drops 0.1% – 1% DV Oct-20 to 20222.20	5 ml	Olopatadine Teva
Note – Patanol eye drops 0.1% to be delisted from 1 October 2020.		

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

VARIOUS

218	CHLORHEXIDINE (delisting) Soln 4%		50 ml	healthE
218	IODINE WITH ETHANOL (delisting) Soln 1% with ethanol 70%, 100 ml9. Note – healthE soln 1% with ethanol 70%, 100 ml to be delisted from		1 nber 2020	healthE
218	CHLORHEXIDINE WITH ETHANOL (delisting) Soln 0.5% with ethanol 70%, non-staining (pink) 100 ml	54 90 86 45 90 56 staining (i		
218	POVIDONE-IODINE (pack size change) Oint 10% – 1% DV Oct-20 to 2023	.40	65 g	Betadine

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

e.g. Nutrison Low Sodium

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

Changes to Section H Part II – effective 1 April 2020

ALIMENTADY TRACT AND METADOLISM

ALIMI	ENTARY 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 (4 price and addition of HSS) Inj 20 mg, 1 ml ampoule – 1% DV Jul-20 to 2023	6.35	5	Buscopan
7	MEBEVERINE HYDROCHLORIDE (4 price and addition of HS Tab 135 mg – 1% DV Jul-20 to 2023		90	Colofac
9	GLUCAGON HYDROCHLORIDE (addition of HSS) Inj 1 mg syringe kit – 1% DV Jul-20 to 2023	32.00	1	Glucagen Hypokit
BL00	D AND BLOOD FORMING ORGANS			
31	ENOXAPARIN SODIUM (Pharmacode change) Inj 20 mg in 0.2 ml syringe Inj 40 mg in 0.4 ml syringe Inj 60 mg in 0.6 ml syringe Inj 80 mg in 0.8 ml syringe Inj 100 mg in 1 ml syringe Inj 120 mg in 0.8 ml syringe Inj 150 mg in 1 ml syringe Note – these are new Pharmacode listings, current Pharmac 389366 and 389390 to be delisted from 1 January 2021.	37.27 56.18 74.90 93.80 116.55 133.20	10 10 10 10 10 10 10 10 795623, 41	Clexane Clexane Clexane Clexane Clexane Clexane Clexane Forte Clexane Forte 6991, 417009, 417017,
31	HEPARIN SODIUM († price) Inj 1,000 iu per ml, 1 ml ampoule Inj 5,000 iu per ml, 1 ml ampoule		50 5	Hospira Hospira
31	HEPARINISED SALINE († price) Inj 10 iu per ml, 5 ml ampoule	65.48	50	Pfizer
31	WARFARIN SODIUM (4 price) Tab 1 mg Tab 3 mg Tab 5 mg	10.03	100 100 100	Marevan Marevan Marevan
34	PEGFILGRASTIM (amended restriction criteria) → Inj 6 mg per 0.6 ml syringe	1,080.00	1	Neulastim

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)		Brand or Generic
 \$	Per	Manufacturer

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 coadministered 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
Inta - Precolal tah 100 mg and 200 mg to be delicted from 1 Sc	ntombor 2	กวก	

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

41 LABETALOL (new listing)

Tab 50 mg

	Price (ex man. Excl.	GST)	Brand or Generic
	\$	Per	Manufacturer
Cha	nges 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	4 4 12 ons; or ons; or ons; and e (PCWP) les pressure (PAR) of at least e to the patie	APm) > 25 mmHg; or 3 Wood Units or at least nt's young age or health
DER	MATOLOGICALS		
55	HYDROCORTISONE (brand change) Crm 1%, 100 g – 1% DV Sep-20 to 2022	100 g	Hydrocortisone (PSM)
56	BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL (new listing) Foam spray 500 mcg with calcipotriol 50 mcg per g59.95	60 g	Enstilar
HOR	RMONE PREPARATIONS		
66	OESTRIOL (new listing and addition of HSS) Tab 2 mg – 1% DV Sep-20 to 20237.00	30	Ovestin

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

INFECTIONS

74	CEFTAROLINE FOSAMIL († price) → Inj 600 mg vial1,595.00	10	Zinforo
76	PIPERACILLIN WITH TAZOBACTAM (new listing) → Inj 4 g with tazobactam 0.5 g vial38.00	10	PiperTaz Sandoz
78	TETRACYCLINE (new listing) Tab 250 mg21.42	28	Accord
78	TETRACYCLINE (delisting) Cap 500 mg46.00 Note – Tetracyclin Wolff cap 500 mg to be delisted from 1 December 2020.	30	Tetracyclin Wolff
84	METRONIDAZOLE (delisting) Tab 200 mg	100 100 020.	Trichozole Trichozole
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	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

[→] Restriction

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

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 ampoule23	3.66	5	Hospira

Brand or Generic Manufacturer

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 Fither:
 - 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

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

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

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130	MITOMYCIN C (amended brand name) Inj 5 mg vial204.08	1	Arrow Teva
131	GEMCITABINE (addition of HSS) Inj 10 mg per ml, 100 ml vial – 1% DV Jul-20 to 202315.89	1	Gemcitabine Ebewe
133	LENALIDOMIDE (new listing)		
	→ Cap 5 mg	28	Revlimid
	→ Cap 10 mg	28	Revlimid
	→ Cap 15 mg	28	Revlimid
133	LENALIDOMIDE (amended restriction criteria)		
	→ Cap 10 mg (↓ price)	21	Revlimid
	→ Cap 15 mg (↓ price)	21	Revlimid
	→ Cap 25 mg	21	Revlimid
	Initiation (Delenged/refractory disease)		

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
- 32 Either
 - 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
- 43 Lenalidomide 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.

Brand or Generic Manufacturer

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)

Restricted

Continuation – pandemic circumstances

Re-assessment required after 6 months

All of the following:

- 1 The patient is clinically benefiting from treatment and continued treatment remains appropriate: and
- 2 Erlotinib to be discontinued at progression; and
- 3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.
- 139 GEFITINIB (amended restriction criteria new criteria shown only)

Restricted

Continuation – pandemic circumstances

Re-assessment required after 6 months

- 1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
- 2 Gefitinib to be discontinued at progression; and
- 3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.

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

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

Reassessment required after 6 months

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 Fither

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

Reassessment required after 12 months

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

Re-assessment required after 6 months

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and
- 2 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
- 3 Sunitinib is to be discontinued at progression; and
- 4 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector.

Price		Brand or
(ex man. Excl. G	ST)	Generic
 \$	Per	Manufacturer

144 ABIRATERONE ACETATE (amended restriction criteria)

Restricted

Initiation

Medical oncologist, radiation oncologist or urologist

Re-assessment required after 6 months

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

Re-assessment required after 6 months

All of the following:

1 Significant decrease in serum PSA from baseline; and

- 12 No evidence of clinical disease progression; and
- 23 No initiation of taxane chemotherapy with abiraterone; and
- **34**The treatment remains appropriate and the patient is benefiting from treatment.

144 VINBLASTINE SULPHATE († price)

145 FULVESTRANT (new listing)

Initiation

Medical Oncologist

Re-assessment required after 6 months

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

Re-assessment required after 6 months

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

145	45 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)

172 MEPOLIZUMAB (new listing)

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

175 RITUXIMAB (MABTHERA) (amended restriction criteria – affected criteria shown only)

Restricted

Continuation – severe cold haemagglutinin disease (CHAD)

Haematologist

Re-assessment required after-4 8 weeks

Fither:

- 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.

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.

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.

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.

Pri	ce		Brand or
(ex man. E	Excl. GST)		Generic
\$	3	Per	Manufacturer

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		Brand or
(ex man. Excl. 6	GST)	Generic
\$	Per	Manufacturer

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.

Brand or Generic Manufacturer

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

Fither:

- 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.

Brand or Generic Manufacturer

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.

Brand or Generic Manufacturer

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 r	ml, 4 ml vial	1,051.	98 1	Opdivo
→ Inj 10 mg per r	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 56 Baseline measurement of overall tumour burden is documented (see Note); and

6.7 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:

Brand or Generic Manufacturer

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
 - 122 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		Brand or
(ex man. Excl. GST)		Generic
\$	Per	Manufacturer

198 PEMBROLIZUMAB (amended restriction criteria)

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 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

Re-assessment required after 4 months

Either:

- 1 All of the following:
 - 1.1 Any of the following:
 - 1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
 - 1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
 - 1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
 - 1.2 Fither:
 - 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.

Brand or Generic Manufacturer

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.

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- 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 benefiting from treatment and continued treatment remains appropriate; and
- 2 Everolimus to be discontinued at progression of SEGAs; and
- 3 The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector. Note: MRI should be performed at minimum once every 12 months, more frequent scanning should be performed with new onset of symptoms such as headaches, visual complaints, nausea or vomiting, or increase in seizure activity.

RESPIRATORY SYSTEM AND ALLERGIES

205 PHOLCODINE (Pharmacode change)
Oral liq 1 mg per ml – 1% DV Jun-20 to 20223.09 200 ml AFT Pholcodine
Linctus BP
Note – this is a new Pharmacode listing 2586932. 2142252 to be delisted from 1 September 2020.

VARIOUS

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

SPEC	CIAL 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	- 200 ml 6.7 g carbol	Pediasure (Chocolate) Pediasure (Strawberry) Pediasure (Vanilla) nydrate and 7.5 q fat per
	100 ml, bottle, 200 ml will no longer be delisted from 1 September 2020.	· ·	
VAC	CINES		
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	5 i ml syringe	ADT Booster to be delisted from
247	HEPATITIS B RECOMBINANT VACCINE (delisting) → Inj 5 mcg in 0.5 ml vial – 0% DV Jul-17 to 2020	1 1 1 per 1 ml vial	HBvaxPR0 HBvaxPR0 HBvaxPR0 to be delisted from
247	HEPATITIS B RECOMBINANT VACCINE (addition of HSS) → Inj 20 mcg per 1 ml prefilled syringe - 0% DV Oct-20 to 2024	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)
Effe	tive 13 March 2020		
NERV	OUS SYSTEM		
111	FLUOXETINE HYDROCHLORIDE († price) Tab dispersible 20 mg, scored9.93	30	Arrow-Fluoxetine

Products with Hospital Supply Status (HSS) are in **bold**. Expiry date of HSS period is 30 June of the year indicated unless otherwise stated.

Index

Pharmaceuticals and brands

A		Entresto 49/51	16
Abciximab	25	Entresto 97/103	16
Abiraterone acetate	24	Eptifibatide	. 4
Adenuric	. 5	Ergotamine tartrate with caffeine	11
ADT Booster	35	Erlotinib	22
Adult diphtheria and tetanus vaccine	35	Esbriet	13
Afinitor		Etanercept	12
AFT Pholcodine Linctus BP		Everolimus	34
Alglucosidase alfa		F	
Arrow-Fluoxetine		Faslodex	24
Arrow-Morphine LA		Febuxostat	
В		Fluox	
Betadine	14	Fluoxetine hydrochloride	
Betadine Skin Prep		Fulvestrant	
Betaine		G	_
Betamethasone dipropionate with calcipotriol		Galsulfase	ç
Bricanyl Turbuhaler		Gefitinib	
Bupivacaine hydrochloride		Gemcitabine 6.	
		Gemcitabine Ebewe 6,	
Buscopan	10		
Calcium carbonate	4	Glucagen Hypokit	
		Glucagon hydrochloride	10
Calcium folinate		••	0.
Cettaroline fosamil		HBvaxPR0	
Cetomacrogol with glycerol		Heparinised saline	
Chlorhexidine		Heparin sodium	
Chlorhexidine gluconate		Hepatitis B recombinant vaccine	
Chlorhexidine with ethanol		Hydrocortisone	
Clexane		Hydrocortisone acetate	
Clexane Forte		Hydrocortisone (PSM)	
Colofac		Hydroxychloroquine	11
Creon Micro		Hyoscine butylbromide	15
Cystadane	. 8	I	
D		Ibrance	
Dacarbazine	11	lmigran	
Dantrium	11	Influenza vaccine	
Dantrium IV		Influvac Tetra (2020 Formulation)	35
Dantrolene	11	Integrilin	
Daunorubicin	11	lodine with ethanol	14
DBL Dacarbazine	11	Iressa	22
DBL Leucovorin Calcium	11	K	
DBL Vincristine Sulfate	12	Keytruda	33
Diazepam11	, 19	Kuvan	. (
Dinoprostone	10	L	
E		Labetalol	16
Emtricitabine with tenofovir disoproxil	18	Lenalidomide	21
Enbrel		Levocarnitine	
Engerix-B		M	•
Enoxaparin sodium		Mabthera	26
Enstilar		Marcain	
Enteral feed 1 kcal/ml		Marevan	
Entresto 24/26		Mebeverine hydrochloride	
LITTI GSTO 24/20	10	mosovomio ny arodinonao	, ,

Index

Pharmaceuticals and brands

Mepolizumab	25	Plaquenil	11
Mesalazine	15	Povidone-iodine	
Metronidazole	18	Povidone-iodine with ethanol	34
Mitomycin C 11	, 21	Primaquine	18
Modafinil	. 6	Primaquine phosphate	18
Modavigil	. 6	Promethazine hydrochloride	12
Morphine sulphate	. 5	Prostin E2	
Mycobutin		R	
Myozyme		ReoPro	25
N		Revlimid	21
Naglazyme	. 8	Rifabutin	10
Neosynephrine HCL		Rituximab (mabthera)	26
Neulastim		Rituximab (riximyo)	
Nintedanib		Riximyo	28
Nivolumab		S	
Nucala		Sacubitril with valsartan	16
Nutrison Low Sodium		Sandostatin LAR	
0		Sapropterin dihydrochloride	
Octreotide	25	Sildenafil	
Oestriol	17	Sodium phenylbutyrate	
Ofev	12	Stesolid	
Olopatadine		Sumatriptan	
Olopatadine Teva		Sunitinib	
Opdivo		Sutent	
Ovestin		T	
Oxytocin		Tarceva	22
Oxytocin BNM		Terbutaline sulphate	
P		Tetracycline	
Paediatric oral feed 1 kcal/ml	35	Tetracyclin Wolff	
Palbociclib		TOBI	
Pancreatic enzyme		Tobramycin	
Pediasure (Chocolate)		Trandate	
Pediasure (Strawberry)		Trichozole	
Pediasure (Vanilla)		V	
Pegfilgrastim	15	Vedafil	17
Pembrolizumab		Vigabatrin	
Pentasa		Vinblastine sulphate	
Pheburane		Vincristine sulphate	
Phenylephrine hydrochloride		W	
Pholcodine		Warfarin sodium	15
Piperacillin with tazobactam		7	
PiperTaz Sandoz		Zinforo	18
Pirfenidone		Zytiga	
1 II I I I I I I I I I I I I I I I I I	.0	_y ugu	4

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