

Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

February 2020

Cumulative for December 2019, January and
February 2020

The logo for PHARMAC, featuring the word "PHARMAC" in a bold, sans-serif font above the Māori name "TE PĀTAKA WHAIORANGA" in a smaller, all-caps sans-serif font. The logo is centered within a white circle that overlaps a large, stylized graphic of white wavy lines on a grey background.

PHARMAC
TE PĀTAKA WHAIORANGA

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Summary of decisions

EFFECTIVE 1 FEBRUARY 2020

- Adrenaline (DBL Adrenaline) inj 1 in 1,000, 1 ml ampoule – price increase
- Apomorphine hydrochloride (Movapo) inj 10 mg per ml, 5 ml ampoule – new listing and addition of HSS
- Aztreonam (Azactam) inj 1 g vial – pack size change from 5 inj pack to 10 inj pack
- Capecitabine (Capercit) tab 150 mg and 500 mg – new listing and addition of HSS
- Capecitabine (Brinov) tab 150 mg and 500 mg – to be delisted 1 July 2020
- Dexamethasone phosphate (Dexamethasone Phosphate Panpharma) inj 4 mg per ml, 1 ml and 2 ml ampoule – new listing and addition of HSS
- Dexamethasone phosphate (Max Health) inj 4 mg per ml, 1 ml and 2 ml ampoule – to be delisted 1 July 2020
- Famotidine inj 10 mg per ml, 2 ml vial – new listing
- Ibuprofen (Ibuprofen SR BNM) tab long-acting 800 mg – new listing and addition of HSS
- Ibuprofen (Brufen SR) tab long-acting 800 mg – to be delisted 1 April 2020
- Influenza vaccine (Afluria Quad Junior (2020 Formulation)) inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) – new listing
- Influenza vaccine (Afluria Quad (2020 Formulation)) inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) – new listing
- Influenza vaccine (Fluarix Tetra) inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) – delisted 1 February 2020
- Influenza vaccine (Influvac Tetra) inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) – delisted 1 February 2020
- Levonorgestrel (Microlut) tab 30 mcg – new listing and addition of HSS
- Low carbohydrate oral feed 1.5 kcal/ml (Pulmocare (Vanilla)) liquid 6.2 g protein, 10.5 g carbohydrate and 9.32 g fat per 100 ml, bottle, 237 ml – to be delisted 1 October 2020
- Metronidazole (Colpocin-T) inj 5 mg per ml, 100 ml bottle – new listing
- Nimodipine (Nimotop) tab 30 mg and inj 200 mcg per ml, 50 ml vial – new listing and addition of HSS
- Olaparib (Lynparza) cap 50 mg, tab 100 mg and 150 mg – new listing
- Paediatric oral feed 1 kcal/ml (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 – to be delisted 1 September 2020

Summary of decisions – effective 1 February 2020 (continued)

- Patent blue V (InterPharma) inj 2.5%, 5 ml prefilled syringe – new listing
- Prednisolone acetate (Prednisolone-AFT) eye drops 1%, 10 ml – price increase
- Rivastigmine (Generic Partners) patch 4.6 mg and 9.5 mg per 24 hour – new listing and addition of HSS
- Rivastigmine (Exelon) patch 4.6 mg and 9.5 mg per 24 hour – to be delisted 1 April 2020
- Rocuronium bromide (DBL Rocuronium Bromide) inj 10 mg per ml, 5 ml vial – price increase
- Tolcapone (Tasmar) tab 100 mg – price increase
- Verapamil hydrochloride (Isoptin SR) tab long-acting 240 mg – new listing
- Verapamil hydrochloride (Verpamil SR) tab long-acting 240 mg – to be delisted 1 September 2020
- Vitamin A with vitamins D and C (e.g. Vitadol C) soln 1,000 u with vitamin D 400 u and ascorbic acid 30 mg per 10 drops – addition of note and to be delisted 1 July 2020

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Section H changes to Part II

Effective 1 February 2020

ALIMENTARY TRACT AND METABOLISM

- 7 FAMOTIDINE (new listing)
Inj 10 mg per ml, 2 ml vial
- 21 VITAMIN A WITH VITAMINS D AND C (addition of note and delisting)
Note: that funding of vitamin A oral liquid can be applied for through the Exceptional Circumstances process; the application form can be found on the PHARMAC website <https://pharmac.govt.nz/assets/form-aphotocopherylacetate-and-vitaminA.pdf>
Soln 1,000 u with vitamin D 400 u
and ascorbic acid 30 mg per 10 drops *e.g. Vitadol C*
Note – Vitadol C soln 1,000 u with vitamin D 400 u and ascorbic acid 30 mg per 10 drops to be delisted from 1 July 2020.

CARDIOVASCULAR SYSTEM

- 43 NIMODIPINE (new listing)
Tab 30 mg – **1% DV Jul-20 to 2022** 350.00 100 **Nimotop**
Inj 200 mcg per ml, 50 ml vial – **1% DV Jul-20 to 2022** 67.50 1 **Nimotop**
- 44 VERAPAMIL HYDROCHLORIDE (brand change)
Tab long-acting 240 mg 15.12 30 Isoptin SR
Note – Verpamil SR tab long-acting 240 mg to be delisted from 1 September 2020.
- 47 ADRENALINE (↑ price)
Inj 1 in 1,000, 1 ml ampoule 10.76 5 DBL Adrenaline

GENITO-URINARY SYSTEM

- 59 LEVONORGESTREL (new listing)
Tab 30 mcg – **1% DV May-20 to 2022** 16.50 84 **Microlut**

HORMONE PREPARATIONS

- 63 DEXAMETHASONE PHOSPHATE (brand change)
Inj 4 mg per ml, 1 ml ampoule – **1% DV Jul-20 to 2022** 9.25 10 **Dexamethasone Phosphate Panpharma**
Inj 4 mg per ml, 2 ml ampoule – **1% DV Jul-20 to 2022** 16.37 10 **Dexamethasone Phosphate Panpharma**

Note – Max Health inj 4 mg per ml, 1 ml and 2 ml ampoule to be delisted from 1 July 2020.

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

INFECTIONS

78	AZTREONAM (pack size change) → Inj 1 g vial.....	364.92	10	Azactam
	Note – Azactam inj 1 g vial, 5 vial pack to be delisted from 1 August 2020.			

84	METRONIDAZOLE (new listing) Inj 5 mg per ml, 100 ml bottle.....	34.80	20	Colpocin-T
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MUSCULOSKELETAL SYSTEM

100	ROCURONIUM BROMIDE († price) Inj 10 mg per ml, 5 ml vial.....	48.01	10	DBL Rocuronium Bromide
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101	IBUPROFEN (brand change) Tab long-acting 800 mg – 1% DV Apr-20 to 2021	5.99	30	Ibuprofen SR BNM
	Note – Brufen SR tab long-acting 800 mg to be delisted from 1 April 2020.			

NERVOUS SYSTEM

103	APOMORPHINE HYDROCHLORIDE (new listing) Inj 10 mg per ml, 5 ml ampoule – 1% DV Feb-20 to 2023	121.84	5	Movapo
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104	TOLCAPONE († price) Tab 100 mg	152.38	100	Tasmar
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125	RIVASTIGMINE (brand change) → Patch 4.6 mg per 24 hour – 1% DV Apr-20 to 2021	48.75	30	Generic Partners
	→ Patch 9.5 mg per 24 hour – 1% DV Apr-20 to 2021	48.75	30	Generic Partners
	Note – Exelon patch 4.6 mg and 9.5 mg per 24 hour to be delisted from 1 April 2020.			

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130	CAPECITABINE (brand change)			
	Tab 150 mg – 1% DV Jul-20 to 2022.....	10.00	60	Capercit
	Tab 500 mg – 1% DV Jul-20 to 2022.....	49.00	120	Capercit
	Note – Brinov tab 150 mg and 500 mg to be delisted from 1 July 2020.			
133	OLAPARIB (new listing)			
	→ Cap 50 mg.....	7,402.00	448	Lynparza
	→ Tab 100 mg.....	3,701.00	56	Lynparza
	→ Tab 150 mg.....	3,701.00	56	Lynparza
	Restriction			
	Initiation			
	Medical Oncologist			
	<i>Re-assessment required after 12 months</i>			
	All of the following:			
	1 Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and			
	2 There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and			
	3 Patient has received at least two lines of previous treatment with platinum-based chemotherapy; and			
	4 Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line of platinum-based chemotherapy; and			
	5 Patient’s disease must have achieved partial or complete response to treatment with the immediately preceding platinum-based regimen; and			
	6 Patient’s disease has not progressed following prior treatment with olaparib; and			
	7 Treatment will be commenced within 8 weeks of the patient’s last dose of the immediately preceding platinum-based regimen; and			
	8 Treatment to be administered as maintenance treatment; and			
	9 Treatment not to be administered in combination with other chemotherapy.			
	Continuation			
	Medical Oncologist			
	<i>Re-assessment required after 12 months</i>			
	All of the following:			
	1 Treatment remains clinically appropriate and patient is benefitting from treatment; and			
	2 No evidence of progressive disease; and			
	3 Treatment to be administered as maintenance treatment; and			
	4 Treatment not to be administered in combination with other chemotherapy.			
	*Note “high-grade serous” includes tumours with high-grade serous features or a high-grade serous component			

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

SENSORY ORGANS

203	PREDNISOLONE ACETATE (↑ price) Eye drops 1%.....	5.93	10 ml	Prednisolone- AFT
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VARIOUS

213	PATENT BLUE V (new listing) Inj 2.5%, 5 ml prefilled syringe.....	420.00	5	InterPharma
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SPECIAL FOODS

230	PAEDIATRIC ORAL FEED 1 KCAL/ML (delisting) → 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 to be delisted from 1 September 2020.

231	LOW CARBOHYDRATE ORAL FEED 1.5 KCAL/ML (delisting) → Liquid 6.2 g protein, 10.5 g carbohydrate and 9.32 g fat per 100 ml, bottle.....	1.66	237 ml	Pulmocare (Vanilla)
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Note – Pulmocare (Vanilla) liquid 6.2 g protein, 10.5 g carbohydrate and 9.32 g fat per 100 ml, bottle, 237 ml 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 February 2020 (continued)

VACCINES

240	INFLUENZA VACCINE (new listing) → Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)	9.00	1	Afluria Quad Junior (2020 Formulation)
	<p>Restricted</p> <p>Initiation – cardiovascular disease for patients aged 6 months to 35 months</p> <p>Any of the following:</p> <ol style="list-style-type: none"> 1 Ischaemic heart disease; or 2 Congestive heart failure; or 3 Rheumatic heart disease; or 4 Congenital heart disease; or 5 Cerebro-vascular disease. <p>Note: hypertension and/or dyslipidaemia without evidence of end-organ disease is excluded from funding.</p> <p>Initiation – chronic respiratory disease for patients aged 6 months to 35 months</p> <p>Either:</p> <ol style="list-style-type: none"> 1 Asthma, if on a regular preventative therapy; or 2 Other chronic respiratory disease with impaired lung function. <p>Note: asthma not requiring regular preventative therapy is excluded from funding.</p> <p>Initiation – Other conditions for patients aged 6 months to 35 months</p> <p>Any of the following:</p> <ol style="list-style-type: none"> 1 Diabetes; or 2 Chronic renal disease; or 3 Any cancer, excluding basal and squamous skin cancers if not invasive; or 4 Autoimmune disease; or 5 Immune suppression or immune deficiency; or 6 HIV; or 7 Transplant recipient; or 8 Neuromuscular and CNS diseases/ disorders; or 9 Haemoglobinopathies; or 10 Is a child on long term aspirin; or 11 Has a cochlear implant; or 12 Errors of metabolism at risk of major metabolic decompensation; or 13 Pre and post splenectomy; or 14 Down syndrome; or 15 Child who has been hospitalised for respiratory illness or has a history of significant respiratory illness. 			
240	INFLUENZA VACCINE (delisted) → Inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine)	9.00	1	Fluarix Tetra
	<p>Note – Fluarix Tetra inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) delisted 1 February 2020.</p>			
240	INFLUENZA VACCINE (brand change) → Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)	90.00	10	Afluria Quad (2020 Formulation)
	<p>Note – Influvac Tetra inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) delisted 1 February 2020.</p>			

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

ALIMENTARY TRACT AND METABOLISM

18	MAGNESIUM SULPHATE (new listing) Inj 100 mg per ml, 50 ml bag			
21	VITAMIN A WITH VITAMINS D AND C (new listing) Soln 1,000 u with vitamin D 400 u and ascorbic acid 30 mg per 10 drops			<i>e.g. Vitadol C</i>
21	RETINOL (new listing) Oral liq 666.7 mcg per 2 drops, 10 ml			

CARDIOVASCULAR SYSTEM

38	ENALAPRIL MALEATE (brand change) Tab 5 mg – 1% DV Jun-20 to 2022.....	1.82	100	Acetec
	Tab 10 mg – 1% DV Jun-20 to 2022.....	2.02	100	Acetec
	Tab 20 mg – 1% DV Jun-20 to 2022.....	2.42	100	Acetec
	Note – Ethics Enalapril tab 5 mg, 10 mg and 20 mg to be delisted from 1 June 2020.			
43	NIFEDIPINE (↑ price) Tab long-acting 20 mg	17.72	100	Nyefax Retard
47	ISOSORBIDE MONONITRATE (↑ price) Tab long-acting 40 mg	8.20	30	Ismo 40 Retard

DERMATOLOGICALS

55	HYDROCORTISONE (↑ price) Crm 1%, 30 g.....	3.42	30 g	DermAssist
	Crm 1%, 500 g.....	17.15	500 g	Pharmacy Health
	Note: DV limit applies to the pack sizes of less than or equal to 100 g.			

INFECTIONS

84	METRONIDAZOLE (pack size change) Inj 5 mg per ml, 100 ml bag.....	55.00	10	Baxter
	Note – Baxter inj 5 mg per ml, 100 ml bag, 48 bag pack to be delisted from 1 April 2020.			

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

NERVOUS SYSTEM

103	APOMORPHINE HYDROCHLORIDE (↓ price and addition of HSS) Inj 10 mg per ml, 2 ml ampoule – 1% DV Jan-20 to 2023	59.50	5	Movapo
106	LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE (brand change) Gel 2%, 11 ml urethral syringe – 1% DV Apr-20 to 2022 Note – Cathejell gel 2%, 10 ml urethral syringe to be delisted from 1 April 2020.	42.00	10	Instillagel Lido
109	MORPHINE SULPHATE (delisting) Tab long-acting 100 mg Note – Arrow-Morphine LA tab long-acting 100 mg to be delisted from 1 March 2020.	6.10	10	Arrow-Morphine LA
112	FLUOXETINE HYDROCHLORIDE (↑ price) Cap 20 mg	7.49	90	Arrow-Fluoxetine
118	LITHIUM CARBONATE (delisting) Tab 250 mg Note – Lithicarb FC tab 250 mg to be delisted from 1 November 2020.	34.30	500	Lithicarb FC

RESPIRATORY SYSTEM AND ALLERGIES

197	PHOLCODINE (new listing) Oral liq 1 mg per ml – 1% DV Jun-20 to 2022	3.09	200 ml	AFT Pholcodine Linctus BP
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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 December 2019

ALIMENTARY TRACT AND METABOLISM

5	SIMETICONE (new listing) Oral drops 40 mg per ml			
20	MULTIVITAMINS (↑ price and addition of HSS) Tab (BPC cap strength) – 1% DV Mar-20 to 2022	11.45	1,000	Mvite
21	ASCORBIC ACID (↑ price and addition of HSS) Tab 100 mg – 1% DV Mar-20 to 2022	9.90	500	Cvite

BLOOD AND BLOOD FORMING ORGANS

27	TRANEXAMIC ACID (brand change) Tab 500 mg – 1% DV May-20 to 2022	9.45	60	Mercury Pharma
Note – Cyklokapron tab 500 mg to be delisted from 1 May 2020.				
31	CLOPIDOGREL (brand change) Tab 75 mg – 1% DV May-20 to 2022	4.60	84	Clopidogrel Multichem
Note – Arrow - Clopid tab 75 mg to be delisted from 1 May 2020.				

CARDIOVASCULAR SYSTEM

41	FLECAINIDE ACETATE (↑ price) Inj 10 mg per ml, 15 ml ampoule	100.00	5	Tambocor
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HORMONE PREPARATIONS

65	DANAZOL (new listing) Cap 100 mg	19.13	28	Mylan
65	DANAZOL (delisting) Cap 100 mg	68.33	100	Azol
Note – Azol cap 100 mg to be delisted from 1 June 2020.				

INFECTIONS

79	METHENAMINE (HEXAMINE) HIPPURATE (new listing and amended chemical name) Tab 1 g	40.01	100	Hiprex
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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 December 2019 (continued)

NERVOUS SYSTEM

111	DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE (new listing) → Cap 25 mg.....	7.83	50	Dosulepin Mylan
112	FLUOXETINE HYDROCHLORIDE (HSS delayed and delisted) Tab dispersible 20 mg, scored – 1% DV Apr-20 to 2022 Cap 20 mg – 1% DV Apr-20 to 2022	1.98 2.91	30 84	Fluox Fluox
Note – Fluox tab dispersible 20 mg, scored and cap 20 mg delisted 1 December 2019 and HSS delayed until 1 August 2020.				
112	FLUOXETINE HYDROCHLORIDE (delisting delayed) Tab dispersible 20 mg, scored..... Cap 20 mg	2.47 1.99	30 90	Arrow-Fluoxetine Arrow-Fluoxetine
Note – delisting delayed from 1 April 2020 until 1 August 2020.				
116	DROPERIDOL (brand change) Inj 2.5 mg per ml, 1 ml ampoule – 1% DV May-20 to 2022	30.95	10	Droleptan
Note – Droperidol Panpharma inj 2.5 mg per ml, 1 ml ampoule to be delisted from 1 May 2020.				
121	OCRELIZUMAB (new listing) → Inj 30 mg per ml, 10 ml vial..... Restricted Initiation Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).	9,346.00	1	Ocrevus

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

130	MITOMYCIN C (new listing) Inj 20 mg vial	816.32	1	Omegapharm
133	COLASPASE [L-ASPARAGINASE] (delisting) Inj 10,000 iu vial..... Note – Leunase inj 10,000 iu vial to be delisted from 1 December 2020.	102.32	1	Leunase
134	PEGASPARGASE (new listing) → Inj 750 iu per ml, 5 ml vial.....	3,005.00	1	Oncaspar LYO
134	PEGASPARGASE (delisting) → Inj 750 iu per ml, 5 ml vial..... Note – Oncaspar inj 750 iu per ml, 5 ml vial to be delisted from 1 May 2020.	3,005.00	1	Oncaspar
134	TEMOZOLOMIDE (brand change) → Cap 5 mg – 1% DV May-20 to 2022	9.13	5	Temaccord
Note – Orion Temozolomide cap 5 mg to be delisted from 1 May 2020.				

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

136	ALECTINIB (new listing) → Cap 150 mg.....	7,935.00	224	Alecensa
	Restricted Initiation <i>Re-assessment required after 6 months</i> All of the following:			
	1 Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer; and			
	2 There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test; and			
	3 Patient has an ECOG performance score of 0-2.			
	Continuation <i>Re-assessment required after 6 months</i> Both:			
	1 No evidence of progressive disease according to RECIST criteria; and			
	2 The patient is benefitting from and tolerating treatment.			
136	VENETOCLAX (new listing) → Tab 10 mg..... → Tab 50 mg..... → Tab 100 mg..... → Tab 14 x 10 mg, 7 x 50 mg, 21 x 100 mg	95.78 239.44 8,209.41 1,771.86	14 7 120 42	Venclexta Venclexta Venclexta Venclexta
	Restricted Initiation - relapsed/refractory chronic lymphocytic leukaemia Haematologist <i>Re-assessment required after 7 months</i> All of the following:			
	1 Patient has chronic lymphocytic leukaemia requiring treatment; and			
	2 Patient has received at least one prior therapy for chronic lymphocytic leukaemia; and			
	3 Patient has not previously received funded venetoclax; and			
	4 The patient's disease has relapsed within 36 months of previous treatment; and			
	5 Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and			
	6 Patient has an ECOG performance status of 0-2.			
	Continuation - relapsed/refractory chronic lymphocytic leukaemia Haematologist <i>Re-assessment required after 6 months</i> Both:			
	1 Treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment; and			
	2 Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity.			
	Initiation - previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation* Haematologist <i>Re-assessment required after 6 months</i> All of the following:			
	1 Patient has previously untreated chronic lymphocytic leukaemia; and			
	2 There is documentation confirming that patient has 17p deletion by FISH testing or TP53 mutation by sequencing; and			
	3 Patient has an ECOG performance status of 0-2.			

continued...

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

continued...

Continuation - previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Haematologist

Re-assessment required after 6 months

The treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)* and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are unapproved indications.

173	RITUXIMAB (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

Initiation – Chronic lymphocytic leukaemia

Re-assessment required after 12 months

All of the following:

1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and

2 Any of the following:

2.1 The patient is rituximab treatment naïve; **and or**

2.2 ~~3~~ Either:

2.2.1 ~~3-1~~ The patient is chemotherapy treatment naïve; or

2.2.2 ~~3-2~~ Both:

2.2.2.1 ~~3-2-1~~ The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and

2.2.2.2 ~~3-2-2~~ The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; **and or**

2.3 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and

3 ~~5~~ The patient has good performance status; and

4 ~~Either:~~

4.1 The patient does not have chromosome 17p deletion CLL; **and or**

4.2 **Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and**

5 ~~6~~ Rituximab to be administered in combination with fludarabine and cyclophosphamide, **or** bendamustine **or venetoclax** for a maximum of 6 treatment cycles; and

6 ~~7~~ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), **or** bendamustine **or venetoclax**.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

Continuation – Chronic lymphocytic leukaemia

Re-assessment required after 12 months

All of the following:

Both:

1 ~~Either:~~

continued...

Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

continued...

1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or

1.2 All of the following:

1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and

1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and

1.2.3 The patient does not have chromosome 17p deletion CLL; and

1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and

2.5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, or bendamustine or **venetoclax** for a maximum of 6 treatment cycles.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

188 TRASTUZUMAB EMTANSINE (new listing)

→ Inj 100 mg vial.....	2,320.00	1	Kadcyla
→ Inj 160 mg vial.....	3,712.00	1	Kadcyla

Restricted

Initiation

Re-assessment required after 6 months

All of the following:

1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and

2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and

3 Either

3.1 The patient has received prior therapy for metastatic disease*; or

3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and

4 Patient has a good performance status (ECOG 0-1); and

5 Either:

5.1 Patient does not have symptomatic brain metastases; or

5.2 Patient has brain metastases and has received prior local CNS therapy; and

6 Treatment to be discontinued at disease progression.

Continuation

Re-assessment required after 6 months

Both:

1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and

2 Treatment to be discontinued at disease progression.

*Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

	Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

188	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		
	<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 the presence of at least one CT or MRI-measurable lesion; 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 for a maximum of 12 weeks (6 cycles); 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 nivolumab will not be continued beyond 12 weeks (6 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; and 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		
	1.5 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks; or for a maximum of 12 weeks (6 cycles).		
	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		

continued...

Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

continued...

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 CT or MRI imaging with 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.

189 PEMBROLIZUMAB (amended restriction criteria)

→ Inj 25 mg per ml, 4 ml vial..... 4,680.00 1 Keytruda

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** ~~the presence of at least one CT or MRI measurable lesion;~~ 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 for a maximum of 12 weeks (4 cycles)**; 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 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:

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 December 2019 (continued)

- 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; ~~and~~ **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
 - 1.5 Pembrolizumab will be used at a maximum dose of **no greater than the equivalent of 2 mg/kg every 3 weeks; or for a maximum of 12 weeks (4 cycles).**
- 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.**

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 ~~CT or MRI imaging with~~ 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.

RESPIRATORY SYSTEM AND ALLERGIES

196	PIRFENIDONE (new listing)		
	→ Tab 801 mg	3,645.00	90 Esbriet

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

196	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 80 90% predicted; and			
	3 Pirfenidone is to be discontinued at disease progression (See Note); 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 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.			

SENSORY ORGANS

201	CHLORAMPHENICOL (brand change)			
	Eye oint 1% – 1% DV May-20 to 2022	1.55	5 g	Devatis
	Note – Chlorsig eye oint 1% to be delisted from 1 May 2020.			

SPECIAL FOODS

232	ENTERAL FEED WITH FIBRE 0.83 KCAL/ML (Pharmacode change and amended presentation description)			
	→ Liquid 5.5 g protein, 8.8 g carbohydrate, 2.5 g fat and 1.5 g fibre per 100 ml, bottle bag	5.29	1,000 ml	Nutrison 800 Complete Multi Fibre
	Note – this is a new Pharmacode listing, 2572982. Pharmacode 2510774 to be delisted from 1 June 2020.			

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

VACCINES

236	MENINGOCOCCAL (A, C, Y AND W-135) CONJUGATE VACCINE (amended restriction criteria) 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 Jul-17 to 2020	0.00	1	Menactra
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Restricted

Initiation

Either:

1 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 HIV, complement deficiency (acquired or inherited), functional or anatomic asplenia or pre or post solid organ transplant; or
- 2 One dose 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 immunosuppression*; **or**

2 Both:

1 Person is aged between 13 and 25 years, inclusive; and

2 Either

2.1 One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons; or

2.2 One dose for individuals who are currently living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons, from 1 December 2019 to 30 November 2020.

Notes: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

243	VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] (amended restriction criteria) → Varicella zoster virus (Oka strain) live attenuated vaccine [shingles vaccine]	0.00	1 10	Zostavax Zostavax
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Restricted

Initiation – people aged between 66 and 80 years

Therapy limited to 1 dose

One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 **Mareh December** 2020.

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New Zealand
Permit No. 478



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