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Editors:

Kaye Wilson, & Doris Chong
email: enquiry@pharmac.govt.nz
Telephone +64 4 460 4990
Level 9, 40 Mercer Street
PO Box 10 254 Wellington

Freephone Information Line

0800 66 00 50 (9am – 5pm weekdays)

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Programmers

Anrik Drenth & John Geering
email: texschedule@pharmac.govt.nz
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Introducing Pharmac

The Pharmaceutical Management Agency (Pharmac) makes decisions that help control Government spending on pharmaceuticals. This includes community pharmaceuticals, hospital pharmaceuticals, vaccines and increasingly, hospital medical devices. Pharmac negotiates prices, sets subsidy levels and conditions, and makes decisions on changes to the subsidised list.

Pharmac's role:

“to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.”

Pae Ora (Healthy Futures) Act 2022

To ensure our decisions are as fair and robust as possible we use a decision-making process that incorporates clinical, economic and commercial issues. We also seek the views of users and the wider community through consultation. The processes we generally use are outlined in our Operating Policies and Procedures.

Further information about Pharmac and the way we make funding decisions can be found on the Pharmac website at

<https://www.pharmac.govt.nz/about>.

Purpose of the Pharmaceutical Schedule

The purpose of the Schedule is to list:

- the Community Pharmaceuticals that are subsidised by the Government and to show the amount of the subsidy paid to contractors, as well as the manufacturer's price and any access conditions that may apply;
- the Hospital Pharmaceuticals that may be used in Health NZ Hospitals, as well as any access conditions that may apply; and
- the Pharmaceuticals, including Medical Devices, used in Health NZ Hospitals for which national prices have been negotiated by Pharmac.

The Schedule does not show the final cost to Government of subsidising each Community Pharmaceutical or to Health NZ Hospitals in purchasing each Pharmaceutical, since that will depend on any rebate and other arrangements Pharmac has with the supplier and, for Pharmaceuticals used in Health NZ Hospitals, on any logistics arrangements put in place.

This book contains sections A to D and Section I of the Pharmaceutical Schedule and lists the Pharmaceuticals funded for use in the community, including vaccines, as well as haemophilia and cancer treatments given in Health NZ hospitals. Section H lists the Pharmaceuticals that can be used in Health NZ hospitals and is a separate publication.

The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

The index lists both chemical entities and product brand names.

Explaining pharmaceutical entries

The Pharmaceutical Schedule lists pharmaceuticals subsidised by the Government, the subsidy, the supplier's price and the access conditions that may apply.

Example

ANATOMICAL HEADING			
THERAPEUTIC HEADING			
CHEMICAL			
Presentation, form and strength		Subsidy (Manufacturer's Price) \$ Per	Fully Brand or Subsidised Generic ✓ Manufacturer
Presentation - Available on a PSO		10.00 100	Brand A ✓ Brand B
Presentation - Retail pharmacy-specialist		15.00 50	✓ Brand C
Presentation - Retail pharmacy-specialist		18.00 250 ml OP	✓ Brand D
a) Prescriptions must be written by a paediatrician or paediatric cardiologist; or b) on the recommendation of a paediatrician or a paediatric cardiologist			
CHEMICAL			
Presentation, form and strength		26.53 100	Brand E
		(35.27)	
Sole Supply/Principal Supply			
Three months supply may be dispensed at one time if endorsed 'certified exemption' by the prescriber or pharmacist.			

Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

Practitioner's Supply Order

Conditions of and restrictions on prescribing (including Special Authority where it applies)

Three months or six months, as applicable, dispensed all-at-once

Brand or manufacturer's name

Sole Subsidised Supply product or Principal Supply Status

Fully subsidised product

Original Pack - Subsidy is rounded up to a multiple of whole packs

Quantity the Subsidy applies to

Subsidy paid on a product before mark-ups and GST

Manufacturer's Price if different from Subsidy

Glossary

Units of Measure

gram	g	microgram.....	mcg	millimole.....	mmol
kilogram.....	kg	milligram	mg	unit.....	u
international unit.....	iu	millilitre.....	ml		

Abbreviations

Ampoule	Amp	Gelatinous	Gel	Solution.....	Soln
Capsule	Cap	Granules	Gran	Suppository.....	Supp
Cream.....	Crm	Infusion	Inf	Tablet.....	Tab
Device.....	Dev	Injection	Inj	Tincture.....	Tinc
Dispersible.....	Disp	Liquid.....	Liq	Trans Dermal Delivery	
Effervescent.....	Eff	Long Acting.....	LA	System.....	TDDS
Emulsion.....	Emul	Ointment.....	Oint		
Enteric Coated.....	EC	Sachet	Sach		

Read the [General Rules](https://www.pharmac.govt.nz/section-a) : <https://www.pharmac.govt.nz/section-a>.

SECTION B: ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Antacids and Antiflatulents

Antacids and Reflux Barrier Agents

ALGINIC ACID

Sodium alginate 225 mg and magnesium alginate 87.5 mg per sachet.....	5.31	30	✓	Gaviscon Infant
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SODIUM ALGINATE

* Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour.....	1.80 (8.60)	60		Gaviscon Double Strength
* Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml.....	1.50 (5.50)	500 ml		Acidex

Phosphate Binding Agents

ALUMINIUM HYDROXIDE

* Tab 600 mg	12.56	100	✓	Alu-Tab
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CALCIUM CARBONATE

Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) – Subsidy by endorsement	39.00	500 ml	✓	Roxane
Only when prescribed for patients unable to swallow calcium carbonate tablets or where calcium carbonate tablets are inappropriate and the prescription is endorsed accordingly.				

Antidiarrhoeals

Agents Which Reduce Motility

LOPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a PSO

* Tab 2 mg	10.75	400	✓	Nodia
* Cap 2 mg	7.25	400	✓	Diamide Relief

Rectal and Colonic Anti-inflammatories

BUDESONIDE

Cap 3 mg – Special Authority see SA1886 below – Retail pharmacy.....	166.50	90	✓	Entocort CIR
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► [SA1886](#) Special Authority for Subsidy

Initial application — (Crohn's disease) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Mild to moderate ileal, ileocaecal or proximal Crohn's disease; and
- 2 Any of the following:
 - 2.1 Diabetes; or
 - 2.2 Cushingoid habitus; or
 - 2.3 Osteoporosis where there is significant risk of fracture; or

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

- 2.4 Severe acne following treatment with conventional corticosteroid therapy; or
- 2.5 History of severe psychiatric problems associated with corticosteroid treatment; or
- 2.6 History of major mental illness (such as bipolar affective disorder) where the risk of conventional corticosteroid treatment causing relapse is considered to be high; or
- 2.7 Relapse during pregnancy (where conventional corticosteroids are considered to be contraindicated).

Initial application — (collagenous and lymphocytic colitis (microscopic colitis)) from any relevant practitioner. Approvals valid for 6 months where patient has a diagnosis of microscopic colitis (collagenous or lymphocytic colitis) by colonoscopy with biopsies.

Initial application — (gut Graft versus Host disease) from any relevant practitioner. Approvals valid for 6 months where patient has a gut Graft versus Host disease following allogeneic bone marrow transplantation*.

Note: Indication marked with * is an unapproved indication.

Initial application — (non-cirrhotic autoimmune hepatitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has autoimmune hepatitis*; and
- 2 Patient does not have cirrhosis; and
- 3 Any of the following:
 - 3.1 Diabetes; or
 - 3.2 Cushingoid habitus; or
 - 3.3 Osteoporosis where there is significant risk of fracture; or
 - 3.4 Severe acne following treatment with conventional corticosteroid therapy; or
 - 3.5 History of severe psychiatric problems associated with corticosteroid treatment; or
 - 3.6 History of major mental illness (such as bipolar affective disorder) where the risk of conventional corticosteroid treatment causing relapse is considered to be high; or
 - 3.7 Relapse during pregnancy (where conventional corticosteroids are considered to be contraindicated); or
 - 3.8 Adolescents with poor linear growth (where conventional corticosteroid use may limit further growth) .

Note: Indication marked with * is an unapproved indication.

Renewal from any relevant practitioner. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (non-cirrhotic autoimmune hepatitis) from any relevant practitioner. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefiting from treatment.

Note: Clinical trials for Entocort CIR use beyond three months demonstrated no improvement in relapse rate.

HYDROCORTISONE ACETATE

Rectal foam 10%, CFC-Free (14 applications).....	26.55	15 g OP 21.1 g OP	✓ Cortifoam ^{\$29} ✓ Colifoam
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HYDROCORTISONE ACETATE WITH PRAMOXINE HYDROCHLORIDE

Topical aerosol foam, 1% with pramoxine hydrochloride 1%.....	26.55	10 g OP	✓ Proctofoam ^{\$29}
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MESALAZINE

Tab 400 mg	49.50	100	✓ Asacol
Tab long-acting 500 mg.....	56.10	100	✓ Pentasa
Tab 800 mg	85.50	90	✓ Asacol
Modified release granules, 1 g	118.10	100 OP	✓ Pentasa
Enema 1 g per 100 ml	41.30	7	✓ Pentasa
Suppos 500 mg	22.80	20	✓ Asacol
Suppos 1 g	50.96	28	✓ Pentasa

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
OLSALAZINE				
Tab 500 mg	56.02	60	✓	Atnahs Olsalazine ^{\$29}
	93.37	100	✓	Dipentum
Cap 250 mg	53.00	100	✓	Dipentum
PREDNISOLONE SODIUM				
Rectal foam 20 mg per dose (14 applications)	74.10	1 OP	✓	Essential Prednisolone ^{\$29}
SODIUM CROMOGLICATE				
Cap 100 mg	92.91	100	✓	Nalcrom ✓ Ralicrom
SULFASALAZINE				
* Tab 500 mg	14.00	100	✓	Salazopyrin
Tab EC 500 mg	15.53	100	✓	Salazopyrin EN

Local preparations for Anal and Rectal Disorders

Antihaemorrhoidal Preparations

FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CINCHOCAINE				
Oint 950 mcg, with fluocortolone pivalate 920 mcg, and cinchocaine hydrochloride 5 mg per g	11.06	30 g OP	✓	Ultraproct
Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and cinchocaine hydrochloride 1 mg	7.30	12	✓	Ultraproct
HYDROCORTISONE WITH CINCHOCAINE				
Oint 5 mg with cinchocaine hydrochloride 5 mg per g	15.00	30 g OP	✓	Proctosedyl
Suppos 5 mg with cinchocaine hydrochloride 5 mg per g	9.90	12	✓	Proctosedyl

Management of Anal Fissures

GLYCERYL TRINITRATE – Special Authority see SA1329 below – Retail pharmacy				
* Oint 0.2%	22.00	30 g OP	✓	Rectogesic

► [SA1329](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has a chronic anal fissure that has persisted for longer than three weeks.

Antispasmodics and Other Agents Altering Gut Motility

GLYCOPYRRONIUM BROMIDE				
Inj 200 mcg per ml, 1 ml ampoule – Up to 10 inj available on a PSO	65.45	10	✓	Max Health
HYOSCINE BUTYLBROMIDE				
* Tab 10 mg	6.35	100	✓	Buscopan
* Inj 20 mg, 1 ml – Up to 5 inj available on a PSO	6.35	5	✓	Buscopan
MEBEVERINE HYDROCHLORIDE				
* Tab 135 mg	9.20	90	✓	Colofac

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Antiulcerants

Antisecretory and Cytoprotective

MISOPROSTOL

* Tab 200 mcg – Up to 120 tab available on a PSO	41.50	120	✓ Cytotec
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Helicobacter Pylori Eradication

CLARITHROMYCIN

Tab 500 mg – Subsidy by endorsement.....	14.58	14	✓ Klacid
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a) Maximum of 28 tab per prescription

b) Subsidised only if prescribed for helicobacter pylori eradication and prescription is endorsed accordingly.

Note: the prescription is considered endorsed if clarithromycin is prescribed in conjunction with a proton pump inhibitor and either amoxicillin or metronidazole.

H2 Antagonists

FAMOTIDINE – Only on a prescription

* Tab 20 mg	4.91	100	✓ Famotidine Hovid <small>\$29</small>
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* Tab 40 mg	8.48	100	✓ Famotidine Hovid <small>\$29</small>
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* Inj 10 mg per ml, 4 ml – Subsidy by endorsement	57.02	10	✓ Mylan <small>\$29</small>
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Subsidy by endorsement – Subsidised for patients receiving treatment as part of palliative care.

Proton Pump Inhibitors

LANSOPRAZOLE

* Cap 15 mg	4.20	100	✓ Lanzol Relief
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* Cap 30 mg	5.26	100	✓ Lanzol Relief
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OMEPRAZOLE

For omeprazole suspension refer Standard Formulae, [page 246](#)

* Cap 10 mg	1.94	90	✓ Omeprazole actavis 10
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* Cap 20 mg	1.86	90	✓ Omeprazole actavis 20
-------------------	------	----	--

* Cap 40 mg	3.11	90	✓ Omeprazole actavis 40
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* Powder – Only in combination.....	42.50	5 g	✓ Midwest
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Only in extemporaneously compounded omeprazole suspension.

* Inj 40 mg ampoule with diluent.....	37.38	5	✓ Dr Reddy's Omeprazole
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PANTOPRAZOLE

* Tab EC 20 mg	2.02	100	✓ Panzop Relief
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* Tab EC 40 mg	2.85	100	✓ Panzop Relief
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Site Protective Agents

COLLOIDAL BISMUTH SUBCITRATE

Tab 120 mg	14.51	50	✓ Gastrodenol <small>\$29</small>
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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
SUCRALFATE				
Tab 1 g	35.50 (48.28)	120		Carafate

Bile and Liver Therapy

RIFAXIMIN – Special Authority see SA1461 below – Retail pharmacy				
Tab 550 mg	625.00	56	✓ Xifaxan	

➔ [SA1461](#) Special Authority for Subsidy

Initial application only from a gastroenterologist, hepatologist or Practitioner on the recommendation of a gastroenterologist or hepatologist. Approvals valid for 6 months where the patient has hepatic encephalopathy despite an adequate trial of maximum tolerated doses of lactulose.

Renewal only from a gastroenterologist, hepatologist or Practitioner on the recommendation of a gastroenterologist or hepatologist. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.

Diabetes

Hyperglycaemic Agents

DIAZOXIDE – Special Authority see SA1320 below – Retail pharmacy				
Cap 25 mg	110.00	100	✓ Proglidem <small>\$29</small>	
Cap 100 mg	280.00	100	✓ Proglidem <small>\$29</small>	
Oral liq 50 mg per ml	620.00	30 ml OP	✓ Proglycem <small>\$29</small>	
			✓ e5 Pharma <small>\$29</small>	

➔ [SA1320](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months where used for the treatment of confirmed hypoglycaemia caused by hyperinsulinism.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.

GLUCAGON HYDROCHLORIDE				
Inj 1 mg syringe kit – Up to 5 kit available on a PSO.....	32.00	1	✓ Glucagen Hypokit	

Insulin - Short-acting Preparations

INSULIN NEUTRAL				
▲ Inj human 100 u per ml.....	25.26	10 ml OP	✓ Actrapid	
			✓ Humulin R	
▲ Inj human 100 u per ml, 3 ml.....	42.66	5	✓ Actrapid Penfill	
			✓ Humulin R	

Insulin - Intermediate-acting Preparations

INSULIN ASPART WITH INSULIN ASPART PROTAMINE				
▲ Inj 100 iu per ml, 3 ml prefilled pen.....	52.15	5	✓ NovoMix 30 FlexPen	
INSULIN ISOPHANE				
▲ Inj human 100 u per ml.....	17.68	10 ml OP	✓ Humulin NPH	
			✓ Protaphane	
▲ Inj human 100 u per ml, 3 ml.....	29.86	5	✓ Humulin NPH	
			✓ Protaphane Penfill	

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
INSULIN ISOPHANE WITH INSULIN NEUTRAL				
▲ Inj human with neutral insulin 100 u per ml	25.26	10 ml OP	✓	Humulin 30/70
			✓	Mixtard 30
▲ Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5	✓	Humulin 30/70
			✓	PenMix 30
			✓	PenMix 40
			✓	PenMix 50

(PenMix 40 Inj human with neutral insulin 100 u per ml, 3 ml to be delisted 1 December 2022)

INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
▲ Inj lispro 25% with insulin lispro protamine 75% 100 u per ml, 3 ml	42.66	5	✓	Humalog Mix 25
▲ Inj lispro 50% with insulin lispro protamine 50% 100 u per ml, 3 ml	42.66	5	✓	Humalog Mix 50

Insulin - Long-acting Preparations

INSULIN GLARGINE				
▲ Inj 100 u per ml, 10 ml	63.00	1	✓	Lantus
▲ Inj 100 u per ml, 3 ml	94.50	5	✓	Lantus
▲ Inj 100 u per ml, 3 ml disposable pen	94.50	5	✓	Lantus SoloStar

Insulin - Rapid Acting Preparations

INSULIN ASPART				
▲ Inj 100 u per ml, 10 ml	30.03	1	✓	NovoRapid
▲ Inj 100 u per ml, 3 ml	51.19	5	✓	NovoRapid Penfill
▲ Inj 100 u per ml, 3 ml syringe	51.19	5	✓	NovoRapid FlexPen
INSULIN GLULISINE				
▲ Inj 100 u per ml, 10 ml	27.03	1	✓	Apidra
▲ Inj 100 u per ml, 3 ml	46.07	5	✓	Apidra
▲ Inj 100 u per ml, 3 ml disposable pen	46.07	5	✓	Apidra SoloStar
INSULIN LISPRO				
▲ Inj 100 u per ml, 10 ml	34.92	10 ml OP	✓	Humalog
▲ Inj 100 u per ml, 3 ml	59.52	5	✓	Humalog

Alpha Glucosidase Inhibitors

ACARBOSE				
* Tab 50 mg	8.95	90	✓	Accarb
* Tab 100 mg	15.29	90	✓	Accarb

Oral Hypoglycaemic Agents

GLIBENCLAMIDE				
* Tab 5 mg	7.50	100	✓	Daonil
GLICLAZIDE				
* Tab 80 mg	15.18	500	✓	Glizide
GLIPIZIDE				
* Tab 5 mg	4.58	100	✓	Minidiab
METFORMIN HYDROCHLORIDE				
* Tab immediate-release 500 mg	14.74	1,000	✓	Metformin Mylan
* Tab immediate-release 850 mg	11.28	500	✓	Metformin Mylan

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PIOGLITAZONE				
* Tab 15 mg	6.80	90	✓	Vexazone
* Tab 30 mg	7.30	90	✓	Vexazone
* Tab 45 mg	12.25	90	✓	Vexazone
VILDAGLIPTIN				
Tab 50 mg	35.00	60	✓	Galvus
VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE				
Tab 50 mg with 1,000 mg metformin hydrochloride	35.00	60	✓	Galvumet
Tab 50 mg with 850 mg metformin hydrochloride	35.00	60	✓	Galvumet

GLP-1 Agonists

►SA2065 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

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

Notes: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.

- a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
- b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m² in the presence of diabetes, without alternative cause.

DULAGLUTIDE – Special Authority see SA2065 above – Retail pharmacy

Note: Not to be given in combination with a funded SGLT-2 inhibitor.

* Inj 1.5mg per 0.5 ml prefilled pen	115.23	4	✓	Trulicity
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SGLT2 Inhibitors

►SA2068 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

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

Notes: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.

- a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
- b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m² in the presence of diabetes, without alternative cause.

EMPAGLIFLOZIN – Special Authority see [SA2068 on the previous page](#) – Retail pharmacy

Note: Not to be given in combination with a funded GLP-1 agonist.

* Tab 10 mg	58.56	30	✓ Jardiance
* Tab 25 mg	58.56	30	✓ Jardiance

EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE – Special Authority see [SA2068 on the previous page](#) – Retail pharmacy

Note: Not to be given in combination with a funded GLP-1 agonist.

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

Diabetes Management

Ketone Testing

BLOOD KETONE DIAGNOSTIC TEST STRIP – Subsidy by endorsement

- a) Not on a BSO
 - b) Maximum of 20 strip per prescription
 - c) Up to 10 strip available on a PSO
 - d) Patient has any of the following:
 - 1) type 1 diabetes; or
 - 2) permanent neonatal diabetes; or
 - 3) undergone a pancreatectomy; or
 - 4) cystic fibrosis-related diabetes; or
 - 5) metabolic disease or epilepsy under the care of a paediatrician, neurologist or metabolic specialist.
- The prescription must be endorsed accordingly.

Test strips	15.50	10 strip OP	✓ KetoSens
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▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Dual Blood Glucose and Blood Ketone Testing

DUAL BLOOD GLUCOSE AND BLOOD KETONE DIAGNOSTIC TEST METER – Subsidy by endorsement

- Maximum of 1 pack per prescription
- Up to 1 pack available on a PSO
- A dual blood glucose and blood ketone diagnostic test meter is subsidised for a patient who has:
 - type 1 diabetes; or
 - permanent neonatal diabetes; or
 - undergone a pancreatectomy; or
 - cystic fibrosis-related diabetes; or
 - metabolic disease or epilepsy under the care of a paediatrician, neurologist or metabolic specialist.

The prescription must be endorsed accordingly. Only 1 meter per patient will be subsidised (no repeat prescriptions). For the avoidance of doubt patients who have previously received a funded meter, other than CareSens, are eligible for a funded CareSens meter.

Meter with 50 lancets, a lancing device and 10 blood glucose

diagnostic test strips.....	20.00	1 OP	✓ CareSens Dual
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Blood Glucose Testing

BLOOD GLUCOSE DIAGNOSTIC TEST METER – Subsidy by endorsement

- Maximum of 1 pack per prescription
- Up to 1 pack available on a PSO
- A diagnostic blood glucose test meter is subsidised for a patient who:
 - is receiving insulin or sulphonylurea therapy; or
 - is pregnant with diabetes; or
 - is on home TPN at risk of hypoglycaemia or hyperglycaemia; or
 - has a genetic or an acquired disorder of glucose homeostasis, excluding type 1 or type 2 diabetes and metabolic syndrome.

The prescription must be endorsed accordingly. Only one CareSens meter per patient will be subsidised (no repeat prescriptions). Patients already using the CareSens N POP meter and CareSens N meter are not eligible for a new meter, unless they have:

- type 1 diabetes; or
- permanent neonatal diabetes; or
- undergone a pancreatectomy; or
- cystic fibrosis-related diabetes.

For the avoidance of doubt patients who have previously received a funded meter, other than CareSens, are eligible for a funded CareSens meter.

Meter with 50 lancets, a lancing device and 10 diagnostic test

strips.....	10.00	1 OP	✓ CareSens N
			✓ CareSens N POP
	20.00		✓ CareSens N Premier

Note: Only 1 meter available per PSO

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

BLOOD GLUCOSE DIAGNOSTIC TEST STRIP – Up to 50 test available on a PSO

The number of test strips available on a prescription is restricted to 50 unless:

- 1) Prescribed for a patient on insulin or a sulphonylurea and endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylurea; or
- 2) Prescribed on the same prescription as insulin or a sulphonylurea in which case the prescription is deemed to be endorsed; or
- 3) Prescribed for a pregnant woman with diabetes and endorsed accordingly; or
- 4) Prescribed for a patient on home TPN at risk of hypoglycaemia or hyperglycaemia and endorsed accordingly; or
- 5) Prescribed for a patient with a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome and endorsed accordingly.

Test strips	10.56	50 test OP	✓ CareSens N ✓ CareSens PRO
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BLOOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)

The number of test strips available on a prescription is restricted to 50 unless:

- 1) Prescribed for a patient on insulin or a sulphonylurea and endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylurea; or
- 2) Prescribed on the same prescription as insulin or a sulphonylurea in which case the prescription is deemed to be endorsed; or
- 3) Prescribed for a pregnant woman with diabetes and endorsed accordingly; or
- 4) Prescribed for a patient on home TPN at risk of hypoglycaemia or hyperglycaemia and endorsed accordingly; or
- 5) Prescribed for a patient with a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome and endorsed accordingly.

Blood glucose test strips.....	26.20	50 test OP	✓ SensoCard
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Insulin Syringes and Needles

Subsidy is available for disposable insulin syringes, needles, and pen needles if prescribed on the same form as the one used for the supply of insulin or when prescribed for an insulin patient and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin.

INSULIN PEN NEEDLES – Maximum of 200 dev per prescription

* 29 g x 12.7 mm	10.95	100	✓ B-D Micro-Fine
* 31 g x 5 mm	12.26	100	✓ B-D Micro-Fine
* 31 g x 6 mm	9.50	100	✓ Berpu
* 31 g x 8 mm	10.95	100	✓ B-D Micro-Fine
* 32 g x 4 mm	10.95	100	✓ B-D Micro-Fine

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
INSULIN SYRINGES, DISPOSABLE WITH ATTACHED NEEDLE – Maximum of 200 dev per prescription				
* Syringe 0.3 ml with 29 g x 12.7 mm needle	13.56	100	✓	B-D Ultra Fine
	1.36	10		
	(1.99)			B-D Ultra Fine
* Syringe 0.3 ml with 31 g x 8 mm needle	13.56	100	✓	B-D Ultra Fine II
	1.30	10		
	(1.99)			B-D Ultra Fine II
* Syringe 0.5 ml with 29 g x 12.7 mm needle	13.56	100	✓	B-D Ultra Fine
	1.36	10		
	(1.99)			B-D Ultra Fine
* Syringe 0.5 ml with 31 g x 8 mm needle	13.56	100	✓	B-D Ultra Fine II
	1.36	10		
	(1.99)			B-D Ultra Fine II
* Syringe 1 ml with 29 g x 12.7 mm needle	13.56	100	✓	B-D Ultra Fine
	1.36	10		
	(1.99)			B-D Ultra Fine
* Syringe 1 ml with 31 g x 8 mm needle	13.56	100	✓	B-D Ultra Fine II
	1.36	10		
	(1.99)			B-D Ultra Fine II

Insulin Pumps

INSULIN PUMP – Special Authority see [SA1603 below](#) – Retail pharmacy

- Maximum of 1 dev per prescription
- Only on a prescription
- Maximum of 1 insulin pump per patient each four year period.

Min basal rate 0.025 U/h	8,800.00	1	✓	MiniMed 770G
Min basal rate 0.1 U/h	4,500.00	1	✓	Tandem t:slim X2 with Basal-IQ

►SA1603 Special Authority for Subsidy

Initial application — (permanent neonatal diabetes) only from a relevant specialist or nurse practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- Patient has permanent neonatal diabetes; and
- A MDI regimen trial is inappropriate; and
- Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- Patient/Parent/Guardian has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
- Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- Either:
 - Applicant is a relevant specialist; or
 - Applicant is a nurse practitioner working within their vocational scope.

Renewal — (permanent neonatal diabetes) only from a relevant specialist or nurse practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- Patient is continuing to derive benefit according to the treatment plan agreed at induction; and
- Patient remains fully compliant and transition to MDI is considered inappropriate by the treating physician; and
- It has been at least 4 years since the last insulin pump received by the patient or, in the case of patients qualifying under previous pump therapy for the initial application; the pump is due for replacement; and

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

4 Either:

- 4.1 Applicant is a relevant specialist; or
- 4.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (severe unexplained hypoglycaemia) only from a relevant specialist or nurse practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has type 1 diabetes or has undergone a pancreatotomy or has cystic fibrosis-related diabetes; and
- 2 Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
- 3 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- 4 Has adhered to an intensive MDI regimen using analogue insulins for at least six months; and
- 5 Has had four severe unexplained hypoglycaemic episodes over a six month period (severe as defined as requiring the assistance of another person); and
- 6 Has an average HbA1c between the following range: equal to or greater than 53 mmol/mol and equal to or less than 90 mmol/mol; and
- 7 Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- 8 Either:
 - 8.1 Applicant is a relevant specialist; or
 - 8.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (severe unexplained hypoglycaemia) only from a relevant specialist or nurse practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction of at least a 50% reduction from baseline in hypoglycaemic events; and
- 2 HbA1c has not increased by more than 5 mmol/mol from baseline; and
- 3 Either:
 - 3.1 It has been at least 4 years since the last insulin pump was received by the patient; or
 - 3.2 The pump is due for replacement; and
- 4 Either:
 - 4.1 Applicant is a relevant specialist; or
 - 4.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (HbA1c) only from a relevant specialist or nurse practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has type 1 diabetes or has undergone a pancreatotomy or has cystic fibrosis-related diabetes; and
- 2 Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
- 3 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- 4 Has adhered to an intensive MDI regimen using analogue insulins for at least six months; and
- 5 Has unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1; and
- 6 In the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment; and
- 7 Has typical HbA1c results between the following range: equal to or greater than 65 mmol/mol and equal to or less than 90 mmol/mol; and
- 8 Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- 9 Either:
 - 9.1 Applicant is a relevant specialist; or

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

9.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (HbA1c) only from a relevant specialist or nurse practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction of achieving and maintaining a reduction in HbA1c from baseline of 10 mmol/mol; and
- 2 The number of severe unexplained recurrent hypoglycaemic episodes has not increased from baseline; and
- 3 Either:
 - 3.1 It has been at least 4 years since the last insulin pump was received by the patient; or
 - 3.2 The pump is due for replacement; and
- 4 Either:
 - 4.1 Applicant is a relevant specialist; or
 - 4.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (Previous use before 1 September 2012) only from a relevant specialist or nurse practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
- 2 Was already on pump treatment prior to 1 September 2012 and had been evaluated by the multidisciplinary team for their suitability for insulin pump therapy at the time of initiating that pump treatment and continues to benefit from pump treatment; and
- 3 The patient has adhered to an intensive MDI regimen using analogue insulins for at least six months prior to initiating pump therapy; and
- 4 The patient is continuing to derive benefit from pump therapy; and
- 5 The patient had achieved and is maintaining a HbA1c of equal to or less than 80 mmol/mol on pump therapy; and
- 6 The patient has had no increase in severe unexplained hypoglycaemic episodes from baseline; and
- 7 The patient's HbA1c has not deteriorated more than 5 mmol/mol from baseline; and
- 8 Either:
 - 8.1 It has been at least 4 years since the last insulin pump was received by the patient; or
 - 8.2 The pump is due for replacement; and
- 9 Either:
 - 9.1 Applicant is a relevant specialist; or
 - 9.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (Previous use before 1 September 2012) only from a relevant specialist or nurse practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient is continuing to derive benefit according to the treatment plan and has maintained a HbA1c of equal to or less than 80 mmol/mol; and
- 2 The patient's HbA1c has not deteriorated more than 5 mmol/mol from the time of commencing pump treatment; and
- 3 The patient has not had an increase in severe unexplained hypoglycaemic episodes from baseline; and
- 4 Either:
 - 4.1 It has been at least 4 years since the last insulin pump was received by the patient; or
 - 4.2 The pump is due for replacement; and
- 5 Either:
 - 5.1 Applicant is a relevant specialist; or
 - 5.2 Applicant is a nurse practitioner working within their vocational scope.

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Insulin Pump Consumables

►SA1985 Special Authority for Subsidy

Initial application — (permanent neonatal diabetes) only from a relevant specialist or nurse practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has permanent neonatal diabetes; and
- 2 A MDI regimen trial is inappropriate; and
- 3 Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- 4 Patient/Parent/Guardian has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
- 5 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- 6 Either:
 - 6.1 Applicant is a relevant specialist; or
 - 6.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (permanent neonatal diabetes) only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction; and
- 2 Patient remains fully compliant and transition to MDI is considered inappropriate by the treating physician; and
- 3 Either:
 - 3.1 Applicant is a relevant specialist; or
 - 3.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (severe unexplained hypoglycaemia) only from a relevant specialist or nurse practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
- 2 Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
- 3 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- 4 Has adhered to an intensive MDI regimen using analogue insulins for at least six months; and
- 5 Has had four severe unexplained hypoglycaemic episodes over a six month period (severe as defined as requiring the assistance of another person); and
- 6 Has an average HbA1c between the following range: equal to or greater than 53 mmol/mol and equal to or less than 90 mmol/mol; and
- 7 Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- 8 Either:
 - 8.1 Applicant is a relevant specialist; or
 - 8.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (severe unexplained hypoglycaemia) only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction of at least a 50% reduction from baseline in hypoglycaemic events; and
- 2 HbA1c has not increased by more than 5 mmol/mol from baseline; and
- 3 Either:
 - 3.1 Applicant is a relevant specialist; or

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

3.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (HbA1c) only from a relevant specialist or nurse practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
- 2 Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
- 3 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- 4 Has adhered to an intensive MDI regimen using analogue insulins for at least six months; and
- 5 Has unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c; and
- 6 In the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment; and
- 7 Has typical HbA1c results between the following range: equal to or greater than 65 mmol/mol and equal to or less than 90 mmol/mol; and
- 8 Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- 9 Either:
 - 9.1 Applicant is a relevant specialist; or
 - 9.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (HbA1c) only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction of achieving and maintaining a reduction in HbA1c from baseline of 10 mmol/mol; and
- 2 The number of severe unexplained recurrent hypoglycaemic episodes has not increased from baseline; and
- 3 Either:
 - 3.1 Applicant is a relevant specialist; or
 - 3.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (Previous use before 1 September 2012) only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
- 2 Was already on pump treatment prior to 1 September 2012 and had been evaluated by the multidisciplinary team for their suitability for insulin pump therapy at the time of initiating that pump treatment and continues to benefit from pump treatment; and
- 3 The patient has adhered to an intensive MDI regimen using analogue insulins for at least six months prior to initiating pump therapy; and
- 4 The patient is continuing to derive benefit from pump therapy; and
- 5 The patient had achieved and is maintaining a HbA1c of equal to or less than 80 mmol/mol on pump therapy; and
- 6 The patient has had no increase in severe unexplained hypoglycaemic episodes from baseline; and
- 7 The patient's HbA1c has not deteriorated more than 5 mmol/mol from baseline; and
- 8 Either:
 - 8.1 Applicant is a relevant specialist; or
 - 8.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (Previous use before 1 September 2012) only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 The patient is continuing to derive benefit according to the treatment plan and has maintained a HbA1c of equal to or less

continued...

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
continued...			
than 80 mmol/mol; and			
2 The patient's HbA1c has not deteriorated more than 5 mmol/mol from initial application; and			
3 The patient has not had an increase in severe unexplained hypoglycaemic episodes from baseline; and			
4 Either:			
4.1 Applicant is a relevant specialist; or			
4.2 Applicant is a nurse practitioner working within their vocational scope.			
INSULIN PUMP CARTRIDGE – Special Authority see SA1985 on page 19 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 packs of cartridge sets will be funded per year.			
Cartridge 300 U, t:lock x 10.....	50.00	1 OP	✓ Tandem Cartridge
INSULIN PUMP INFUSION SET (STEEL CANNULA) – Special Authority see SA1985 on page 19 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 infusion sets will be funded per year.			
10 mm steel needle; 60 cm tubing x 10	130.00	1 OP	✓ MiniMed Sure-T MMT-884A
10 mm steel needle; 80 cm tubing x 10	130.00	1 OP	✓ MiniMed Sure-T MMT-886A
6 mm steel needle; 60 cm tubing x 10	130.00	1 OP	✓ MiniMed Sure-T MMT-864A
6 mm steel needle; 80 cm tubing x 10	130.00	1 OP	✓ MiniMed Sure-T MMT-866A
8 mm steel needle; 60 cm tubing x 10	130.00	1 OP	✓ MiniMed Sure-T MMT-874A
8 mm steel needle; 80 cm tubing x 10	130.00	1 OP	✓ MiniMed Sure-T MMT-876A
6 mm steel needle; 29 G; manual insertion; 60 cm tubing x 10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-863
8 mm steel needle; 29 G; manual insertion; 60 cm tubing x 10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-873
INSULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT INSERTION) – Special Authority see SA1985 on page 19 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 infusion sets will be funded per year.			
6 mm steel cannula; straight insertion; 80 cm line x 10 with 10 needles	130.00	1 OP	✓ TruSteel
8 mm steel cannula; straight insertion; 80 cm line x 10 with 10 needles	130.00	1 OP	✓ TruSteel
6 mm steel cannula; straight insertion; 60 cm line x 10 with 10 needles	130.00	1 OP	✓ TruSteel
8 mm steel cannula; straight insertion; 60 cm line x 10 with 10 needles	130.00	1 OP	✓ TruSteel

ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
INSULIN PUMP INFUSION SET (TEFLON CANNULA) – Special Authority see SA1985 on page 19 – Retail pharmacy				
a) Maximum of 3 set per prescription				
b) Only on a prescription				
c) Maximum of 13 infusion sets will be funded per year.				
13 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	✓	MiniMed Silhouette MMT-382A
13 mm teflon needle, 45 cm tubing × 10	130.00	1 OP	✓	MiniMed Silhouette MMT-368A
13 mm teflon needle, 60 cm tubing × 10	130.00	1 OP	✓	MiniMed Silhouette MMT-381A
13 mm teflon needle, 80 cm tubing × 10	130.00	1 OP	✓	MiniMed Silhouette MMT-383A
17 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	✓	MiniMed Silhouette MMT-377A
17 mm teflon needle, 60 cm tubing × 10	130.00	1 OP	✓	MiniMed Silhouette MMT-378A
17 mm teflon needle, 80 cm tubing × 10	130.00	1 OP	✓	MiniMed Silhouette MMT-384A
6 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	✓	MiniMed Quick-Set MMT-398A
6 mm teflon needle, 45 cm blue tubing × 10	130.00	1 OP	✓	MiniMed Mio MMT-941A
6 mm teflon needle, 45 cm pink tubing × 10	130.00	1 OP	✓	MiniMed Mio MMT-921A
6 mm teflon needle, 60 cm blue tubing × 10	130.00	1 OP	✓	MiniMed Mio MMT-943A
6 mm teflon needle, 60 cm pink tubing × 10	130.00	1 OP	✓	MiniMed Mio MMT-923A
6 mm teflon needle, 60 cm tubing × 10	130.00	1 OP	✓	MiniMed Quick-Set MMT-399A
6 mm teflon needle, 80 cm blue tubing	130.00	1 OP	✓	MiniMed Mio MMT-945A
6 mm teflon needle, 80 cm clear tubing × 10	130.00	1 OP	✓	MiniMed Mio MMT-965A
6 mm teflon needle, 80 cm pink tubing × 10	130.00	1 OP	✓	MiniMed Mio MMT-925A
6 mm teflon needle, 80 cm tubing × 10	130.00	1 OP	✓	MiniMed Quick-Set MMT-387A
9 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	✓	MiniMed Quick-Set MMT-396A
9 mm teflon needle, 60 cm tubing × 10	130.00	1 OP	✓	MiniMed Quick-Set MMT-397A
9 mm teflon needle, 80 cm clear tubing × 10	130.00	1 OP	✓	MiniMed Mio MMT-975A
9 mm teflon needle, 80 cm tubing × 10	130.00	1 OP	✓	MiniMed Quick-Set MMT-386A

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION WITH INSERTION DEVICE) – Special Authority see SA1985 on page 19 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 infusion sets will be funded per year.			
13 mm teflon cannula; angle insertion; insertion device; 110 cm line x 10 with 10 needles	140.00	1 OP	✓ AutoSoft 30
13 mm teflon cannula; angle insertion; insertion device; 60 cm line x 10 with 10 needles	140.00	1 OP	✓ AutoSoft 30
INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION) – Special Authority see SA1985 on page 19 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 infusion sets will be funded per year.			
17 mm teflon cannula; angle insertion; 60 cm line x 10 with 10 needles; luer lock	130.00	1 OP	✓ Silhouette MMT-373
INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION WITH INSERTION DEVICE) – Special Authority see SA1985 on page 19 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 infusion sets will be funded per year.			
6 mm teflon cannula; straight insertion; insertion device; 110 cm line x 10 with 10 needles	140.00	1 OP	✓ AutoSoft 90
6 mm teflon cannula; straight insertion; insertion device; 60 cm line x 10 with 10 needles	140.00	1 OP	✓ AutoSoft 90
9 mm teflon cannula; straight insertion; insertion device; 110 cm line x 10 with 10 needles	140.00	1 OP	✓ AutoSoft 90
9 mm teflon cannula; straight insertion; insertion device; 60 cm line x 10 with 10 needles	140.00	1 OP	✓ AutoSoft 90
INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION) – Special Authority see SA1985 on page 19 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 infusion sets will be funded per year.			
6 mm teflon cannula; straight insertion; 60 cm tubing x 10 with 10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-393
9 mm teflon cannula; straight insertion; 60 cm tubing x 10 with 10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-392
INSULIN PUMP RESERVOIR – Special Authority see SA1985 on page 19 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 packs of reservoir sets will be funded per year.			
10 x luer lock conversion cartridges 1.8 ml for Paradigm pumps	50.00	1 OP	✓ ADR Cartridge 1.8
Cartridge for 5 and 7 series pump; 1.8 ml x 10	50.00	1 OP	✓ MiniMed 1.8 Reservoir MMT-326A
Cartridge for 7 series pump; 3.0 ml x 10	50.00	1 OP	✓ MiniMed 3.0 Reservoir MMT-332A

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Digestives Including Enzymes

PANCREATIC ENZYME

Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase 10,000 Ph Eur U, total protease 600 Ph Eur U)	34.93	100	✓	Creon 10000
Cap pancreatin (175 mg (25,000 U lipase, 22,500 U amylase, 1,250 U protease))	94.40	100	✓	Panzytrat
Cap pancreatin 300 mg (amylase 18,000 Ph Eur U, lipase 25,000 Ph Eur U, total protease 1,000 Ph Eur U)	94.38	100	✓	Creon 25000
Modified release granules pancreatin 60.12 mg (amylase 3,600 Ph Eur U, lipase 5,000 Ph Eur U, protease 200 Ph Eur U)	34.93	20 g OP	✓	Creon Micro
<i>(Panzytrat Cap pancreatin (175 mg (25,000 U lipase, 22,500 U amylase, 1,250 U protease)) to be delisted 1 June 2023)</i>				

URSODEOXYCHOLIC ACID – Special Authority see [SA1739 below](#) – Retail pharmacy

Cap 250 mg	32.95	100	✓	Ursosan
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► [SA1739](#) Special Authority for Subsidy

Initial application — (Alagille syndrome or progressive familial intrahepatic cholestasis) from any relevant practitioner.

Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 Patient has been diagnosed with Alagille syndrome; or
- 2 Patient has progressive familial intrahepatic cholestasis.

Initial application — (Chronic severe drug induced cholestatic liver injury) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has chronic severe drug induced cholestatic liver injury; and
- 2 Cholestatic liver injury not due to Total Parenteral Nutrition (TPN) use in adults; and
- 3 Treatment with ursodeoxycholic acid may prevent hospital admission or reduce duration of stay.

Initial application — (Primary biliary cholangitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Primary biliary cholangitis confirmed by antimitochondrial antibody titre (AMA) > 1:80, and raised cholestatic liver enzymes with or without raised serum IgM or, if AMA is negative, by liver biopsy; and
- 2 Patient not requiring a liver transplant (bilirubin > 100 umol/l; decompensated cirrhosis).

Initial application — (Pregnancy) from any relevant practitioner. Approvals valid for 6 months where the patient diagnosed with cholestasis of pregnancy.

Initial application — (Haematological Transplant) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient at risk of veno-occlusive disease or has hepatic impairment and is undergoing conditioning treatment prior to allogeneic stem cell or bone marrow transplantation; and
- 2 Treatment for up to 13 weeks.

Initial application — (Total parenteral nutrition induced cholestasis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Paediatric patient has developed abnormal liver function as indicated on testing which is likely to be induced by Total Parenteral Nutrition (TPN); and
- 2 Liver function has not improved with modifying the TPN composition.

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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continued...

Renewal — (Chronic severe drug induced cholestatic liver injury) from any relevant practitioner. Approvals valid for 6 months where the patient continues to benefit from treatment.

Renewal — (Pregnancy/Primary biliary cholangitis) from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (Total parenteral nutrition induced cholestasis) from any relevant practitioner. Approvals valid for 6 months where the paediatric patient continues to require TPN and who is benefiting from treatment, defined as a sustained improvement in bilirubin levels.

Note: Ursodeoxycholic acid is not an appropriate therapy for patients requiring a liver transplant (bilirubin > 100 micromol/l; decompensated cirrhosis). These patients should be referred to an appropriate transplant centre. Treatment failure -- doubling of serum bilirubin levels, absence of a significant decrease in ALP or ALT and AST, development of varices, ascites or encephalopathy, marked worsening of pruritus or fatigue, histological progression by two stages, or to cirrhosis, need for transplantation.

Laxatives

Bulk-forming Agents

ISPAGHULA (PSYLLIUM) HUSK – Only on a prescription

* Powder for oral soln.....	6.00	250 g OP	✓ Macro Organic Psyllium Husk
	12.20	500 g OP	✓ Konsyl-D

MUCILAGINOUS LAXATIVES WITH STIMULANTS

* Dry.....	6.02 (17.32)	500 g OP	Normacol Plus
	2.41 (8.72)	200 g OP	Normacol Plus

Faecal Softeners

DOCUSATE SODIUM – Only on a prescription

* Tab 50 mg	2.31	100	✓ Coloxyl
* Tab 120 mg	3.13	100	✓ Coloxyl

DOCUSATE SODIUM WITH SENNOSIDES

Tab 50 mg with sennosides 8 mg	3.50	200	✓ Laxsol
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POLOXAMER – Only on a prescription

Not funded for use in the ear.			
* Oral drops 10%.....	3.98	30 ml OP	✓ Coloxyl

Opioid Receptor Antagonists - Peripheral

METHYLNALTREXONE BROMIDE – Special Authority see [SA1691 below](#) – Retail pharmacy

Inj 12 mg per 0.6 ml vial	36.00	1	✓ Relistor
	246.00	7	✓ Relistor

► **SA1691** Special Authority for Subsidy

Initial application — (Opioid induced constipation) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 1 The patient is receiving palliative care; and
- 2 Either:
 - 2.1 Oral and rectal treatments for opioid induced constipation are ineffective; or
 - 2.2 Oral and rectal treatments for opioid induced constipation are unable to be tolerated.

Osmotic Laxatives

GLYCEROL

* Suppos 3.6 g – Only on a prescription	9.25	20	✓ PSM
* Suppos 4 g – Only on a prescription	10.39	20	✓ Lax-suppositories Glycerol

(PSM Suppos 3.6 g to be delisted 1 February 2023)

LACTULOSE – Only on a prescription

* Oral liq 10 g per 15 ml	3.33	500 ml	✓ Laevolac
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MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BICARBONATE AND SODIUM CHLORIDE

Powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg	6.70	30	✓ <u>Molaxole</u>
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SODIUM ACID PHOSPHATE – Only on a prescription

Enema 16% with sodium phosphate 8%	2.50	1	✓ Fleet Phosphate Enema
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SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE – Only on a prescription

Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml	29.98	50	✓ Micolette ✓ Micolette-S29 ^{S29}
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Stimulant Laxatives

BISACODYL – Only on a prescription

* Tab 5 mg	5.80	200	✓ Bisacodyl Viatris ✓ Pharmacy Health
* Suppos 10 mg	3.69	10	✓ <u>Lax-Suppositories</u>

(Pharmacy Health Tab 5 mg to be delisted 1 January 2023)

SENNA – Only on a prescription

* Tab, standardised	2.17 (8.21)	100	
	0.43 (2.06)	20	Senokot Senokot

SODIUM PICOSULFATE – Special Authority see SA2053 below – Retail pharmacy

Oral soln 7.5 mg per ml	7.40	30 ml OP	✓ Dulcolax SP Drop
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►SA2053 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
Both:

- 1 The patient is a child with problematic constipation despite an adequate trial of other oral pharmacotherapies including macrogol where practicable; and
- 2 The patient would otherwise require a high-volume bowel cleansing preparation or hospital admission.

Renewal from any relevant practitioner. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Metabolic Disorder Agents

ALGLUCOSIDASE ALFA – Special Authority see [SA1986 below](#) – Retail pharmacy

Inj 50 mg vial	1,142.60	1	✓ Myozyme
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►SA1986 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 12 months for applications meeting the following criteria:

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.

Renewal only from a metabolic physician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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

ARGININE – Special Authority see [SA2042 below](#) – Retail pharmacy

Tab 1,000 mg	CBS	90	✓ Clinicians
Cap 500 mg	CBS	50	✓ Solgar
Powder	CBS	400 g	✓ Biomed

►SA2042 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 6 months where patient has a suspected inborn error of metabolism that may respond to arginine supplementation.

Renewal only from a metabolic physician. Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The patient has a confirmed diagnosis of an inborn error of metabolism that responds to arginine supplementation; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

BETAINE – Special Authority see [SA1987 on the next page](#) – Retail pharmacy

Powder for oral soln.....	575.00	180 g OP	✓ Cystadane
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1987 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 12 months for applications meeting the following criteria:
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.

Renewal only from a metabolic physician. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

COENZYME Q10 – Special Authority see [SA2039 below](#) – Retail pharmacy

Cap 120 mg.....	CBS	30	✓ Solgar
Cap 160 mg.....	CBS	60	✓ Go Healthy

►SA2039 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 6 months where patient has a suspected inborn error of metabolism that may respond to coenzyme Q10 supplementation.

Renewal only from a metabolic physician. Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The patient has a confirmed diagnosis of an inborn error of metabolism that responds to coenzyme Q10 supplementation; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

GALSULFASE – Special Authority see [SA1988 below](#) – Retail pharmacy

Inj 1 mg per ml, 5 ml vial.....	2,234.00	1	✓ Naglazyme
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►SA1988 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 12 months for applications meeting the following criteria:
Both:

- 1 The patient has been diagnosed with mucopolysaccharidosis VI; and
- 2 Either:
 - 2.1 Diagnosis confirmed by demonstration of N-acetyl-galactosamine-4-sulfatase (arylsulfatase B) deficiency 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.

Renewal only from a metabolic physician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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

IDURSULFASE – Special Authority see [SA1623 on the next page](#) – Retail pharmacy

Inj 2 mg per ml, 3 ml vial.....	4,608.30	1	✓ Elaprase
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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►SA1623 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 24 weeks for applications meeting the following criteria:
All of the following:

- 1 The patient has been diagnosed with Hunter Syndrome (mucopolysaccharidosis II); and
- 2 Either:
 - 2.1 Diagnosis confirmed by demonstration of iduronate 2-sulfatase deficiency in white blood cells by either enzyme assay in cultured skin fibroblasts; or
 - 2.2 Detection of a disease causing mutation in the iduronate 2-sulfatase gene; and
- 3 Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with idursulfase would be bridging treatment to transplant; and
- 4 Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT); and
- 5 Idursulfase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 weeks post-HSCT) at doses no greater than 0.5 mg/kg every week.

LARONIDASE – Special Authority see SA1695 below – Retail pharmacy

Inj 100 U per ml, 5 ml vial	1,335.16	1	✓ Aldurazyme
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►SA1695 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 24 weeks for applications meeting the following criteria:
All of the following:

- 1 The patient has been diagnosed with Hurler Syndrome (mucopolysaccharidosis I-H); and
- 2 Either:
 - 2.1 Diagnosis confirmed by demonstration of alpha-L-iduronidase deficiency in white blood cells by either enzyme assay in cultured skin fibroblasts; or
 - 2.2 Detection of two disease causing mutations in the alpha-L-iduronidase gene and patient has a sibling who is known to have Hurler syndrome; and
- 3 Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with laronidase would be bridging treatment to transplant; and
- 4 Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT); and
- 5 Laronidase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 post-HSCT) at doses no greater than 100 units/kg every week.

LEVOCARNITINE – Special Authority see SA2040 below – Retail pharmacy

Tab 500 mg	CBS	30	✓ Solgar
Cap 250 mg	CBS	30	✓ Solgar
Cap 500 mg	CBS	60	✓ Balance
Oral liq 1 g per 10 ml	CBS	118 ml	✓ Carnitor S29
Oral liq 500 mg per 10 ml	CBS	300 ml	✓ Balance

►SA2040 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 6 months where patient has a suspected inborn error of metabolism that may respond to carnitine supplementation.

Renewal only from a metabolic physician. Approvals valid for 24 months for applications meeting the following criteria:
Both:

- 1 The patient has a confirmed diagnosis of an inborn error of metabolism that responds to carnitine supplementation; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

RIBOFLAVIN – Special Authority see SA2041 on the next page – Retail pharmacy

Tab 100 mg	CBS	100	✓ Country Life
Cap 100 mg	CBS	100	✓ Solgar

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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►SA2041 Special Authority for Subsidy

Initial application only from a metabolic physician or neurologist. Approvals valid for 6 months where patient has a suspected inborn error of metabolism that may respond to riboflavin supplementation.

Renewal only from a metabolic physician or neurologist. Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The patient has a confirmed diagnosis of an inborn error of metabolism that responds to riboflavin supplementation; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

SAPROPTERIN DIHYDROCHLORIDE – Special Authority see [SA1989 below](#) – Retail pharmacy

Tab soluble 100 mg 1,452.70 30 OP ✓ **Kuvan**

►SA1989 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 1 month for applications meeting the following criteria: 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.

Renewal only from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician.

Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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

SODIUM BENZOATE – Special Authority see [SA1599 below](#) – Retail pharmacy

Soln 100 mg per ml CBS 100 ml ✓ **Amzoate** S29

►SA1599 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 12 months where the patient has a diagnosis of a urea cycle disorder.

Renewal only from a metabolic physician. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

SODIUM PHENYLBUTYRATE – Special Authority see [SA1990 on the next page](#) – Retail pharmacy

Grans 483 mg per g 2,016.00 174 g OP ✓ **Pheburane**

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1990 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 12 months where the patient has a diagnosis of a urea cycle disorder involving a deficiency of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase.

Renewal only from a metabolic physician. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

TAURINE – Special Authority see [SA2043 below](#) – Retail pharmacy

Cap 500 mg	CBS	50	✓ Solgar
Cap 1,000 mg	CBS	90	✓ Life Extension
Powder	CBS	300 g	✓ Life Extension

►SA2043 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 6 months where patient has a suspected specific mitochondrial disorder that may respond taurine supplementation.

Renewal only from a metabolic physician. Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The patient has confirmed diagnosis of a specific mitochondrial disorder which responds to taurine supplementation; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Gaucher's Disease

TALIGLUCERASE ALFA – Special Authority see [SA2137 below](#) – Retail pharmacy

Inj 200 unit vial	1,072.00	1	✓ Elelyso
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►SA2137 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has a diagnosis of symptomatic type 1 or type 3* Gaucher disease confirmed by the demonstration of specific deficiency of glucocerebrosidase in leukocytes or cultured skin fibroblasts, and genotypic analysis; and
- 2 Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by enzyme replacement therapy (ERT) or the disease might be reasonably expected to compromise a response to ERT; and
- 3 Any of the following:
 - 3.1 Patient has haematological complications of Gaucher disease; or
 - 3.2 Patient has skeletal complications of Gaucher disease; or
 - 3.3 Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease; or
 - 3.4 Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease; or
 - 3.5 Patient is a child and has experienced growth failure with significant decrease in percentile linear growth over a 6-12 month period; and
- 4 Taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units).

Note: Indication marked with * is an unapproved indication

Renewal only from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician.

Approvals valid for 3 years for applications meeting the following criteria:

All of the following:

- 1 Patient has demonstrated a symptomatic improvement and has maintained improvements in the main symptom or symptoms for which therapy was started; and
- 2 Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size; and

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 3 Radiological (MRI) signs of bone activity performed at two years since initiation of treatment, and five yearly thereafter, demonstrate no deterioration shown by the MRI, compared with MRI taken immediately prior to commencement of therapy or adjusted dose; and
- 4 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
- 5 Patient is adherent with regular treatment and taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units).

Mouth and Throat

Agents Used in Mouth Ulceration

BENZYDAMINE HYDROCHLORIDE

Soln 0.15% – Higher subsidy of \$20.31 per 500 ml with

Endorsement	9.00	500 ml	
	(20.31)		Diffiam

Additional subsidy by endorsement for a patient who has oral mucositis as a result of treatment for cancer, and the prescription is endorsed accordingly.

CARMELLOSE SODIUM WITH GELATIN AND PECTIN

Paste	17.20	56 g OP	✓ Stomahesive
	4.55	15 g OP	
	(7.90)		Orabase
	1.52	5 g OP	
	(3.60)		Orabase
Powder	8.48	28 g OP	
	(10.95)		Stomahesive

CHOLINE SALICYLATE WITH CETALKONIUM CHLORIDE

* Adhesive gel 8.7% with cetalkonium chloride 0.01%	2.06	15 g OP	
	(6.00)		Bonjela

TRIAMCINOLONE ACETONIDE

Paste 0.1%	5.33	5 g OP	✓ Kenalog in Orabase
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Oropharyngeal Anti-infectives

AMPHOTERICIN B

Lozenges 10 mg	5.86	20	✓ Fungilin
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MICONAZOLE

Oral gel 20 mg per g	4.74	40 g OP	✓ Decozol
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NYSTATIN

Oral liq 100,000 u per ml	1.76	24 ml OP	✓ Niostat
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Vitamins				
Vitamin B				
HYDROXOCOBALAMIN				
* Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PSO	1.89	3	✓	Vita-B12
	2.46		✓	Hydroxocobalamin Panpharma
	2.84		✓	Neo-B12
	3.15	5	✓	Hydroxocobalamin Mercury Pharma
<i>(Vita-B12 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 November 2022)</i>				
<i>(Neo-B12 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 November 2022)</i>				
<i>(Hydroxocobalamin Mercury Pharma Inj 1 mg per ml, 1 ml ampoule to be delisted 1 November 2022)</i>				
PYRIDOXINE HYDROCHLORIDE				
a) No more than 100 mg per dose				
b) Only on a prescription				
* Tab 25 mg – No patient co-payment payable.....	2.70	90	✓	Vitamin B6 25
Tab 50 mg	23.45	500	✓	Pyridoxine multichem
THIAMINE HYDROCHLORIDE – Only on a prescription				
* Tab 50 mg	7.09	100	✓	Max Health
VITAMIN B COMPLEX				
* Tab, strong, BPC.....	7.15	500	✓	Bplex
Vitamin C				
ASCORBIC ACID				
a) No more than 100 mg per dose				
b) Only on a prescription				
* Tab 100 mg	12.50	500	✓	Cvite
Vitamin D				
ALFACALCIDOL				
* Cap 0.25 mcg	26.32	100	✓	One-Alpha
* Cap 1 mcg	87.98	100	✓	One-Alpha
* Oral drops 2 mcg per ml.....	60.68	20 ml OP	✓	One-Alpha S29 S29
CALCITRIOL				
* Cap 0.25 mcg	7.89	100	✓	Calcitriol-AFT
Calcitriol-AFT to be Principal Supply on 1 December 2022				
* Cap 0.5 mcg	13.68	100	✓	Calcitriol-AFT
Calcitriol-AFT to be Principal Supply on 1 December 2022				
COLECALCIFEROL				
* Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescription.....	2.95	12	✓	Vit.D3
* Oral liq 188 mcg per ml (7,500 iu per ml)	9.00	4.8 ml OP	✓	Puria

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Multivitamin Preparations

MULTIVITAMIN RENAL – Special Authority see [SA1546 below](#) – Retail pharmacy

* Cap.....	6.49	30	✓ Clinicians Renal Vit
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► [SA1546](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient has chronic kidney disease and is receiving either peritoneal dialysis or haemodialysis; or
- 2 The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of < 15 ml/min/1.73 m² body surface area (BSA).

MULTIVITAMINS – Special Authority see [SA1036 below](#) – Retail pharmacy

* Powder	72.00	200 g OP	✓ Paediatric Seravit
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► [SA1036](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where patient has had a previous approval for multivitamins.

VITAMINS

* Tab (BPC cap strength).....	18.50	1,000	✓ Mvite
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* Cap (fat soluble vitamins A, D, E, K) – Special Authority see SA1720 below – Retail pharmacy	23.40	60	✓ Vitabdeck
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► [SA1720](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Patient has cystic fibrosis with pancreatic insufficiency; or
- 2 Patient is an infant or child with liver disease or short gut syndrome; or
- 3 Patient has severe malabsorption syndrome.

Minerals

Calcium

CALCIUM CARBONATE

* Tab 1.25 g (500 mg elemental)	6.69	250	✓ Calci-Tab 500
* Tab eff 1.25 g (500 mg elemental) – Subsidy by endorsement.....	260.00	100	✓ Calcium 500 mg Hexal ^{S29}

Subsidy by endorsement – Only when prescribed for paediatric patients (< 5 years) where calcium carbonate oral liquid is considered unsuitable.

CALCIUM GLUCONATE

* Inj 10%, 10 ml ampoule.....	32.00	10	✓ Max Health - Hameln ^{S29}
	64.00	20	✓ Max Health ^{S29}

Fluoride

SODIUM FLUORIDE

* Tab 1.1 mg (0.5 mg elemental)	8.64	100	✓ PSM
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(PSM Tab 1.1 mg (0.5 mg elemental) to be delisted 1 March 2023)

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Iodine				
POTASSIUM IODATE				
* Tab 253 mcg (150 mcg elemental iodine)	4.58	90	✓	NeuroTabs
Iron				
FERROUS FUMARATE				
* Tab 200 mg (65 mg elemental)	3.04	100	✓	Ferro-tab
FERROUS FUMARATE WITH FOLIC ACID				
* Tab 310 mg (100 mg elemental) with folic acid 350 mcg	5.98	100	✓	Ferro-F-Tabs
FERROUS SULFATE				
* Tab long-acting 325 mg (105 mg elemental)	2.55	30	✓	Ferrograd
* Oral liq 30 mg (6 mg elemental) per 1 ml	13.10	500 ml	✓	Ferodan
IRON (AS FERRIC CARBOXYMALTOSE) – Special Authority see SA1840 below – Retail pharmacy				
Inj 50 mg per ml, 10 ml vial	150.00	1	✓	Ferinject
►SA1840 Special Authority for Subsidy				
Initial application — (serum ferritin less than or equal to 20 mcg/L) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:				
Both:				
1 Patient has been diagnosed with iron-deficiency anaemia with a serum ferritin level of less than or equal to 20 mcg/L; and				
2 Any of the following:				
2.1 Patient has been compliant with oral iron treatment and treatment has proven ineffective; or				
2.2 Treatment with oral iron has resulted in dose-limiting intolerance; or				
2.3 Rapid correction of anaemia is required.				
Renewal — (serum ferritin less than or equal to 20 mcg/L) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:				
Both:				
1 Patient continues to have iron-deficiency anaemia with a serum ferritin level of less than or equal to 20 mcg/L; and				
2 A re-trial with oral iron is clinically inappropriate.				
Initial application — (iron deficiency anaemia) only from an internal medicine physician, obstetrician, gynaecologist, anaesthetist or medical practitioner on the recommendation of a internal medicine physician, obstetrician, gynaecologist or anaesthetist. Approvals valid for 3 months for applications meeting the following criteria:				
Both:				
1 Patient has been diagnosed with iron-deficiency anaemia; and				
2 Any of the following:				
2.1 Patient has been compliant with oral iron treatment and treatment has proven ineffective; or				
2.2 Treatment with oral iron has resulted in dose-limiting intolerance; or				
2.3 Patient has symptomatic heart failure, chronic kidney disease stage 3 or more or active inflammatory bowel disease and a trial of oral iron is unlikely to be effective; or				
2.4 Rapid correction of anaemia is required.				
Renewal — (iron deficiency anaemia) only from an internal medicine physician, obstetrician, gynaecologist, anaesthetist or medical practitioner on the recommendation of a internal medicine physician, obstetrician, gynaecologist or anaesthetist. Approvals valid for 3 months for applications meeting the following criteria:				
Both:				
1 Patient continues to have iron-deficiency anaemia; and				
2 A re-trial with oral iron is clinically inappropriate.				
IRON POLYMALTOSE				
* Inj 50 mg per ml, 2 ml ampoule	34.50	5	✓	Ferrosig

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Magnesium				
MAGNESIUM HYDROXIDE				
Suspension 8%.....	33.60	355 ml	✓	Phillips Milk of Magnesia ^{\$29}
MAGNESIUM SULPHATE				
* Inj 2 mmol per ml, 5 ml ampoule	25.53	10	✓	Martindale
Zinc				
ZINC SULPHATE				
* Cap 137.4 mg (50 mg elemental)	11.00	100	✓	Zincaps

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Antianaemics

Hypoplastic and Haemolytic

►SA1775 Special Authority for Subsidy

Initial application — (chronic renal failure) from any specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient in chronic renal failure; and
- 2 Haemoglobin is less than or equal to 100g/L; and
- 3 Any of the following:
 - 3.1 Both:
 - 3.1.1 Patient does not have diabetes mellitus; and
 - 3.1.2 Glomerular filtration rate is less than or equal to 30ml/min; or
 - 3.2 Both:
 - 3.2.1 Patient has diabetes mellitus; and
 - 3.2.2 Glomerular filtration rate is less than or equal to 45ml/min; or
 - 3.3 Patient is on haemodialysis or peritoneal dialysis.

Note: Epoetin alfa is indicated in the treatment of anaemia associated with chronic renal failure (CRF) where no cause for anaemia other than CRF is detected and there is adequate monitoring of iron stores and iron replacement therapy.

Initial application — (myelodysplasia) from any specialist. Approvals valid for 2 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a confirmed diagnosis of myelodysplasia (MDS)*; and
- 2 Has had symptomatic anaemia with haemoglobin < 100g/L and is red cell transfusion-dependent; and
- 3 Patient has very low, low or intermediate risk MDS based on the WHO classification based prognostic scoring system for myelodysplastic syndrome (WPSS); and
- 4 Other causes of anaemia such as B12 and folate deficiency have been excluded; and
- 5 Patient has a serum epoetin level of < 500 IU/L; and
- 6 The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week.

Note: Indication marked with * is an unapproved indication

Renewal — (chronic renal failure) from any specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Note: Epoetin alfa is indicated in the treatment of anaemia associated with chronic renal failure (CRF) where no cause for anaemia other than CRF is detected and there is adequate monitoring of iron stores and iron replacement therapy.

Renewal — (myelodysplasia) from any specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient's transfusion requirement continues to be reduced with erythropoietin treatment; and
- 2 Transformation to acute myeloid leukaemia has not occurred; and
- 3 The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week.

Note: Indication marked with * is an unapproved indication

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

BLOOD AND BLOOD FORMING ORGANS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
EPOETIN ALFA – Special Authority see SA1775 on the previous page – Retail pharmacy				
Wastage claimable				
Inj 1,000 iu in 0.5 ml, syringe.....	250.00	6	✓	Binocrit
Inj 2,000 iu in 1 ml, syringe.....	100.00	6	✓	Binocrit
Inj 3,000 iu in 0.3 ml, syringe.....	150.00	6	✓	Binocrit
Inj 4,000 iu in 0.4 ml, syringe.....	96.50	6	✓	Binocrit
Inj 5,000 iu in 0.5 ml, syringe.....	125.00	6	✓	Binocrit
Inj 6,000 iu in 0.6 ml, syringe.....	145.00	6	✓	Binocrit
Inj 8,000 iu in 0.8 ml, syringe.....	175.00	6	✓	Binocrit
Inj 10,000 iu in 1 ml, syringe.....	197.50	6	✓	Binocrit
Inj 40,000 iu in 1 ml, syringe.....	250.00	1	✓	Binocrit

Megaloblastic

FOLIC ACID				
Tab 0.8 mg	26.60	1,000	✓	Folic Acid multichem
* Tab 5 mg	5.82	100	✓	Folic Acid Mylan
Oral liq 50 mcg per ml	27.82	25 ml OP	✓	Biomed

Antifibrinolytics, Haemostatics and Local Sclerosants

EFTRENONACOG ALFA [RECOMBINANT FACTOR IX] – [Xpharm]

For patients with haemophilia B receiving prophylaxis treatment. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management group.

Inj 250 iu vial.....	612.50	1	✓	Alprolix
Inj 500 iu vial.....	1,225.00	1	✓	Alprolix
Inj 1,000 iu vial.....	2,450.00	1	✓	Alprolix
Inj 2,000 iu vial.....	4,900.00	1	✓	Alprolix
Inj 3,000 iu vial.....	7,350.00	1	✓	Alprolix
Inj 4,000 iu vial.....	9,800.00	1	✓	Alprolix

ELTROMBOPAG – Special Authority see [SA1743 below](#) – Retail pharmacy

Wastage claimable				
Tab 25 mg	1,550.00	28	✓	Revolade
Tab 50 mg	3,100.00	28	✓	Revolade

►SA1743 Special Authority for Subsidy

Initial application — (idiopathic thrombocytopenic purpura - post-splenectomy) only from a haematologist. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has had a splenectomy; and
- 2 Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab); and
- 3 Any of the following:
 - 3.1 Patient has a platelet count of 20,000 to 30,000 platelets per microlitre and has evidence of significant mucocutaneous bleeding; or
 - 3.2 Patient has a platelet count of less than or equal to 20,000 platelets per microlitre and has evidence of active bleeding; or
 - 3.3 Patient has a platelet count of less than or equal to 10,000 platelets per microlitre.

Initial application — (idiopathic thrombocytopenic purpura - preparation for splenectomy) only from a haematologist.

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

Approvals valid for 6 weeks where the patient requires eltrombopag treatment as preparation for splenectomy.

Initial application — (idiopathic thrombocytopenic purpura contraindicated to splenectomy) only from a haematologist.

Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a significant and well-documented contraindication to splenectomy for clinical reasons; and
- 2 Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab); and
- 3 Either:
 - 3.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microliter; or
 - 3.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding.

Initial application — (severe aplastic anaemia) only from a haematologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Two immunosuppressive therapies have been trialled and failed after therapy of at least 3 months duration; and
- 2 Either:
 - 2.1 Patient has severe aplastic anaemia with a platelet count of less than or equal to 20,000 platelets per microliter; or
 - 2.2 Patient has severe aplastic anaemia with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding.

Renewal — (idiopathic thrombocytopenic purpura - post-splenectomy) only from a haematologist. Approvals valid for 12 months where the patient has obtained a response (see Note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.

Note: Response to treatment is defined as a platelet count of > 30,000 platelets per microlitre.

Renewal — (idiopathic thrombocytopenic purpura contraindicated to splenectomy) only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient's significant contraindication to splenectomy remains; and
- 2 The patient has obtained a response from treatment during the initial approval period; and
- 3 Patient has maintained a platelet count of at least 50,000 platelets per microlitre on treatment; and
- 4 Further treatment with eltrombopag is required to maintain response.

Renewal — (severe aplastic anaemia) only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has obtained a response from treatment of at least 20,000 platelets per microlitre above baseline during the initial approval period; and
- 2 Platelet transfusion independence for a minimum of 8 weeks during the initial approval period.

EMICIZUMAB – [Xpharm] – Special Authority see [SA1969 below](#)

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

►SA1969 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe congenital haemophilia A and history of bleeding and bypassing agent usage within the last six months; and

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

2 Either:

- 2.1 Patient has had greater than or equal to 6 documented and treated spontaneous bleeds within the last 6 months if on an on-demand bypassing agent regimen; or
- 2.2 Patient has had greater than or equal to 2 documented and treated spontaneous bleeds within the last 6 months if on a bypassing agent prophylaxis regimen; and

3 Patient has a high-titre inhibitor to Factor VIII (greater than or equal to 5 Bethesda units per ml) which has persisted for six months or more; and

4 There is no immediate plan for major surgery within the next 12 months; and

5 Either:

- 5.1 Patient has failed immune tolerance induction (ITI) after an initial period of 12 months; or
- 5.2 The Haemophilia Treaters Group considers the patient is not a suitable candidate for ITI; and

6 Treatment is to be administered at a maximum dose of 3 mg/kg weekly for 4 weeks followed by the equivalent of 1.5 mg/kg weekly.

Renewal only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

EPTACOG ALFA [RECOMBINANT FACTOR VIIA] – [Xpharm]

For patients with haemophilia. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group. Rare Clinical Circumstances Brand of bypassing agent for > 14 days predicted use. Access to funded treatment for > 14 days predicted use is by named patient application to the Haemophilia Treaters Group, subject to access criteria.

Inj 1 mg syringe	1,178.30	1	✓ NovoSeven RT
Inj 2 mg syringe	2,356.60	1	✓ NovoSeven RT
Inj 5 mg syringe	5,891.50	1	✓ NovoSeven RT
Inj 8 mg syringe	9,426.40	1	✓ NovoSeven RT

FACTOR EIGHT INHIBITOR BYPASSING FRACTION – [Xpharm]

For patients with haemophilia. Preferred Brand of bypassing agent for > 14 days predicted use. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

Inj 500 U	1,315.00	1	✓ FEIBA NF
Inj 1,000 U	2,630.00	1	✓ FEIBA NF
Inj 2,500 U	6,575.00	1	✓ FEIBA NF

MOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] – [Xpharm]

For patients with haemophilia. Rare Clinical Circumstances Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group, subject to criteria.

Inj 250 iu prefilled syringe	287.50	1	✓ Xyntha
Inj 500 iu prefilled syringe	575.00	1	✓ Xyntha
Inj 1,000 iu prefilled syringe	1,150.00	1	✓ Xyntha
Inj 2,000 iu prefilled syringe	2,300.00	1	✓ Xyntha
Inj 3,000 iu prefilled syringe	3,450.00	1	✓ Xyntha

NONACOG GAMMA, [RECOMBINANT FACTOR IX] – [Xpharm]

For patients with haemophilia. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

Inj 500 iu vial	435.00	1	✓ RIXUBIS
Inj 1,000 iu vial	870.00	1	✓ RIXUBIS
Inj 2,000 iu vial	1,740.00	1	✓ RIXUBIS
Inj 3,000 iu vial	2,610.00	1	✓ RIXUBIS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE) – [Xpharm]				
For patients with haemophilia. Preferred Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.				
Inj 250 iu vial.....	210.00	1	✓	Advate
Inj 500 iu vial.....	420.00	1	✓	Advate
Inj 1,000 iu vial.....	840.00	1	✓	Advate
Inj 1,500 iu vial.....	1,260.00	1	✓	Advate
Inj 2,000 iu vial.....	1,680.00	1	✓	Advate
Inj 3,000 iu vial.....	2,520.00	1	✓	Advate
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENATE FS) – [Xpharm]				
For patients with haemophilia. Rare Clinical Circumstances Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group, subject to criteria.				
Inj 250 iu vial.....	237.50	1	✓	Kogenate FS
Inj 500 iu vial.....	475.00	1	✓	Kogenate FS
Inj 1,000 iu vial.....	950.00	1	✓	Kogenate FS
Inj 2,000 iu vial.....	1,900.00	1	✓	Kogenate FS
Inj 3,000 iu vial.....	2,850.00	1	✓	Kogenate FS
RURIOCTOCOG ALFA PEGOL [RECOMBINANT FACTOR VIII] – [Xpharm]				
For patients with haemophilia A receiving prophylaxis treatment. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management group.				
Inj 250 iu vial.....	300.00	1	✓	Adynovate
Inj 500 iu vial.....	600.00	1	✓	Adynovate
Inj 1,000 iu vial.....	1,200.00	1	✓	Adynovate
Inj 2,000 iu vial.....	2,400.00	1	✓	Adynovate
SODIUM TETRADECYL SULPHATE				
* Inj 3% 2 ml.....	28.50 (73.00)	5		Fibro-vein
TRANEXAMIC ACID				
Tab 500 mg.....	9.45	60	✓	Mercury Pharma
Vitamin K				
PHYTOMENADIONE				
Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSO.....	8.00	5	✓	Konakion MM
Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO.....	9.21	5	✓	Konakion MM
Antithrombotic Agents				
Antiplatelet Agents				
ASPIRIN				
* Tab 100 mg.....	10.80	990	✓	Ethics Aspirin EC
CLOPIDOGREL				
* Tab 75 mg.....	4.60	84	✓	Clopidogrel Multichem
DIPYRIDAMOLE				
* Tab long-acting 150 mg.....	10.90	60	✓	Pytazen SR
TICAGRELOR – Special Authority see SA1955 on the next page – Retail pharmacy				
* Tab 90 mg.....	90.00	56	✓	Brilinta

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1955 Special Authority for Subsidy

Initial application — (acute coronary syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient has recently (within the last 60 days) been diagnosed with an ST-elevation or a non-ST-elevation acute coronary syndrome; and
- 2 Fibrinolytic therapy has not been given in the last 24 hours and is not planned.

Initial application — (thrombosis prevention neurological stenting) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 Patient has had a neurological stenting procedure* in the last 60 days; or
 - 1.2 Patient is about to have a neurological stenting procedure performed*; and
- 2 Either:
 - 2.1 Patient has demonstrated clopidogrel resistance using the P2Y12 (VerifyNow) assay or another appropriate platelet function assay and requires antiplatelet treatment with ticagrelor; or
 - 2.2 Either:
 - 2.2.1 Clopidogrel resistance has been demonstrated by the occurrence of a new cerebral ischemic event; or
 - 2.2.2 Clopidogrel resistance has been demonstrated by the occurrence of transient ischemic attack symptoms referable to the stent.

Initial application — (Percutaneous coronary intervention with stent deployment) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has undergone percutaneous coronary intervention; and
- 2 Patient has had a stent deployed in the previous 4 weeks; and
- 3 Patient is clopidogrel-allergic**.

Initial application — (Stent thrombosis) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has experienced cardiac stent thrombosis whilst on clopidogrel.

Renewal — (subsequent acute coronary syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient has recently (within the last 60 days) been diagnosed with an ST-elevation or a non-ST-elevation acute coronary syndrome; and
- 2 Fibrinolytic therapy has not been given in the last 24 hours and is not planned.

Renewal — (thrombosis prevention neurological stenting) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient is continuing to benefit from treatment; and
- 2 Treatment continues to be clinically appropriate.

Renewal — (Percutaneous coronary intervention with stent deployment) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has undergone percutaneous coronary intervention; and
- 2 Patient has had a stent deployed in the previous 4 weeks; and
- 3 Patient is clopidogrel-allergic**.

Notes: indications marked with * are unapproved indications.

Note: ** Clopidogrel allergy is defined as a history of anaphylaxis, urticaria, generalised rash or asthma (in non-asthmatic patients) developing soon after clopidogrel is started and is considered unlikely to be caused by any other treatment.

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Heparin and Antagonist Preparations

ENOXAPARIN SODIUM – Special Authority see [SA2152 below](#) – Retail pharmacy

Inj 20 mg in 0.2 ml syringe.....	31.28	10	✓ Clexane
Inj 40 mg in 0.4 ml syringe.....	42.49	10	✓ Clexane
Inj 60 mg in 0.6 ml syringe.....	60.67	10	✓ Clexane
Inj 80 mg in 0.8 ml syringe.....	80.89	10	✓ Clexane
Inj 100 mg in 1 ml syringe.....	101.30	10	✓ Clexane
Inj 120 mg in 0.8 ml syringe.....	125.87	10	✓ Clexane Forte
Inj 150 mg in 1 ml syringe.....	143.86	10	✓ Clexane Forte

►SA2152 Special Authority for Subsidy

Initial application — (Pregnancy, Malignancy or Haemodialysis) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Low molecular weight heparin treatment is required during a patients pregnancy; or
- 2 For the treatment of venous thromboembolism where the patient has a malignancy; or
- 3 For the prevention of thrombus formation in the extra-corporeal circulation during haemodialysis.

Initial application — (Venous thromboembolism other than in pregnancy or malignancy) from any relevant practitioner.

Approvals valid for 1 month for applications meeting the following criteria:

Any of the following:

- 1 For the short-term treatment of venous thromboembolism prior to establishing a therapeutic level of oral anti-coagulant treatment; or
- 2 For the prophylaxis and treatment of venous thromboembolism in high risk surgery; or
- 3 To enable cessation/re-establishment of existing oral anticoagulant treatment pre/post surgery; or
- 4 For the prophylaxis and treatment of venous thromboembolism in Acute Coronary Syndrome surgical intervention; or
- 5 To be used in association with cardioversion of atrial fibrillation.

Initial application — (Short-term use during treatment of COVID-19 with nirmatrelvir with ritonavir) from any relevant practitioner. Approvals valid for 2 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient is receiving an anticoagulation treatment that has drug/drug interactions with ritonavir that increases risk of bleeding; and
- 2 Patient meets the Access Criteria for COVID-19 antivirals published on the Pharmac website*; and
- 3 Other antiviral treatments for COVID-19 have been considered and are not clinically suitable options.

Renewal — (Pregnancy, Malignancy or Haemodialysis) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Low molecular weight heparin treatment is required during a patient's pregnancy; or
- 2 For the treatment of venous thromboembolism where the patient has a malignancy; or
- 3 For the prevention of thrombus formation in the extra-corporeal circulation during haemodialysis.

Renewal — (Venous thromboembolism other than in pregnancy or malignancy) from any relevant practitioner. Approvals valid for 1 month where low molecular weight heparin treatment or prophylaxis is required for a second or subsequent event (surgery, ACS, cardioversion, or prior to oral anti-coagulation).

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

BLOOD AND BLOOD FORMING ORGANS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
HEPARIN SODIUM				
Inj 1,000 iu per ml, 5 ml ampoule	72.84	50	✓	Pfizer
Inj 5,000 iu per ml, 1 ml	32.66	5	✓	DBL Heparin Sodium <small>\$29</small>
	70.33		✓	Hospira
Inj 5,000 iu per ml, 5 ml ampoule	289.05	50	✓	Pfizer
Inj 25,000 iu per ml, 0.2 ml	22.42	5	✓	Hospira
	42.40		✓	Heparin DBL <small>\$29</small>
	482.20	50	✓	Heparin DBL <small>\$29</small>
HEPARINISED SALINE				
Inj 10 iu per ml, 5 ml	65.48	50	✓	Pfizer

Oral Anticoagulants

DABIGATRAN				
Cap 75 mg – No more than 2 cap per day	76.36	60	✓	Pradaxa
Cap 110 mg	76.36	60	✓	Pradaxa
Cap 150 mg	76.36	60	✓	Pradaxa
RIVAROXABAN				
Tab 10 mg – No more than 1 tab per day	83.10	30	✓	Xarelto
Tab 15 mg – Up to 14 tab available on a PSO	77.56	28	✓	Xarelto
Tab 20 mg	77.56	28	✓	Xarelto
WARFARIN SODIUM				
Note: Marevan and Coumadin are not interchangeable.				
* Tab 1 mg	3.46	50	✓	Coumadin
	6.46	100	✓	Marevan
* Tab 2 mg	4.31	50	✓	Coumadin
* Tab 3 mg	10.03	100	✓	Marevan
* Tab 5 mg	5.93	50	✓	Coumadin
	11.48	100	✓	Marevan

Blood Colony-stimulating Factors

FILGRASTIM – Special Authority see SA1259 below – Retail pharmacy				
Inj 300 mcg per 0.5 ml prefilled syringe	96.22	10	✓	Nivestim
Inj 480 mcg per 0.5 ml prefilled syringe	148.58	10	✓	Nivestim

► [SA1259](#) Special Authority for Subsidy

Initial application only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 20%); or
- 2 Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation; or
- 3 Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation; or
- 4 Treatment of severe chronic neutropenia ($ANC < 0.5 \times 10^9/L$); or
- 5 Treatment of drug-induced prolonged neutropenia ($ANC < 0.5 \times 10^9/L$).

Note: *Febrile neutropenia risk greater than or equal to 20% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

PEGFILGRASTIM – Special Authority see SA1912 on the next page – Retail pharmacy				
Inj 6 mg per 0.6 ml syringe	1,080.00	1	✓	Neulastim

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1912 Special Authority for Subsidy

Initial application only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where used for prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 5%*).

Note: *Febrile neutropenia risk greater than or equal to 5% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

Fluids and Electrolytes

Intravenous Administration

GLUCOSE [DEXTROSE]

* Inj 50%, 10 ml ampoule – Up to 5 inj available on a PSO	30.65	5	✓ Biomed
* Inj 50%, 90 ml bottle – Up to 5 inj available on a PSO	15.00	1	✓ Biomed

POTASSIUM CHLORIDE

* Inj 75 mg per ml, 10 ml	65.00	50	✓ Juno
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SODIUM BICARBONATE

Inj 8.4%, 50 ml	21.40	1	✓ Biomed
a) Up to 5 inj available on a PSO			
b) Not in combination			
Inj 8.4%, 100 ml	21.95	1	✓ Biomed
a) Up to 5 inj available on a PSO			
b) Not in combination			

SODIUM CHLORIDE

Not funded for use as a nasal drop. Not funded for nebuliser use except when used in conjunction with an antibiotic intended for nebuliser use.

Inj 0.9%, bag – Up to 2000 ml available on a PSO	1.23	500 ml	✓ Baxter
	1.26	1,000 ml	✓ Baxter

Only if prescribed on a prescription for renal dialysis, maternity or post-natal care in the home of the patient, or on a PSO for emergency use. (500 ml and 1,000 ml packs)

Inj 23.4% (4 mmol/ml), 20 ml ampoule	35.50	5	✓ Biomed
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For Sodium chloride oral liquid formulation refer Standard Formulae, [page 246](#)

Inj 0.9%, 5 ml ampoule – Up to 5 inj available on a PSO	4.00	20	✓ Fresenius Kabi
Inj 0.9%, 10 ml ampoule – Up to 5 inj available on a PSO	5.25	50	✓ Fresenius Kabi
Inj 0.9%, 20 ml ampoule	5.00	20	✓ Fresenius Kabi

TOTAL PARENTERAL NUTRITION (TPN)

Infusion	CBS	1 OP	✓ TPN
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WATER

- 1) On a prescription or Practitioner's Supply Order only when on the same form as an injection listed in the Pharmaceutical Schedule requiring a solvent or diluent; or
- 2) On a bulk supply order; or
- 3) When used in the extemporaneous compounding of eye drops; or
- 4) When used for the dilution of sodium chloride soln 7% for cystic fibrosis patients only.

Inj 10 ml ampoule – Up to 5 inj available on a PSO	7.19	50	✓ Pfizer
Inj 20 ml ampoule – Up to 5 inj available on a PSO	5.00	20	✓ Fresenius Kabi
			✓ Multichem

(Multichem Inj 20 ml ampoule to be delisted 1 January 2023)

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Oral Administration				
CALCIUM POLYSTYRENE SULPHONATE				
Powder	169.85	300 g OP	✓	Calcium Resonium
COMPOUND ELECTROLYTES				
Powder for oral soln – Up to 5 sach available on a PSO.....	9.53	50	✓	Electral
Electral to be Principal Supply on 1 December 2022				
COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE]				
Soln with electrolytes (2 x 500 ml)	6.55	1,000 ml OP	✓	Pedialyte - Bubblegum
PHOSPHORUS				
Tab eff 500 mg (16 mmol)	82.50	100	✓	Phosphate Phebra
POTASSIUM CHLORIDE				
* Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq).....	5.26 (17.10)	60		Chlorvescent
* Tab long-acting 600 mg (8 mmol).....	8.90	200	✓	Span-K
SODIUM BICARBONATE				
Cap 840 mg.....	8.52	100	✓	Sodibic
			✓	Sodibic
SODIUM POLYSTYRENE SULPHONATE				
Powder	84.65	454 g OP	✓	Resonium-A

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
Alpha-Adrenoceptor Blockers			
Alpha Adrenoceptor Blockers			
DOXAZOSIN			
* Tab 2 mg	17.35	500	✓ Doxazosin Clinect
* Tab 4 mg	20.94	500	✓ Doxazosin Clinect
PHENOXYBENZAMINE HYDROCHLORIDE			
* Cap 10 mg	65.00	30	✓ BNM ^{\$29}
	216.67	100	✓ Dibenzyline ^{\$29}
PRAZOSIN			
* Tab 1 mg	5.53	100	✓ Arrotex-Prazosin \$29 ^{\$29}
* Tab 2 mg	7.00	100	✓ Arrotex-Prazosin \$29 ^{\$29}
* Tab 5 mg	11.70	100	✓ Arrotex-Prazosin \$29 ^{\$29}
Agents Affecting the Renin-Angiotensin System			
ACE Inhibitors			
CAPTOPRIL			
* Oral liq 5 mg per ml	94.99	95 ml OP	✓ Capoten
Oral liquid restricted to children under 12 years of age.			
CILAZAPRIL – Subsidy by endorsement			
Subsidy by endorsement – Subsidised for patients who were taking cilazapril prior to 1 May 2021 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of cilazapril.			
* Tab 0.5 mg	2.09	90	✓ Zapril
* Tab 2.5 mg	4.80	90	✓ Zapril
Tab 5 mg	8.35	90	✓ Zapril
ENALAPRIL MALEATE			
* Tab 5 mg	1.82	100	✓ Acetec
* Tab 10 mg	2.02	100	✓ Acetec
* Tab 20 mg	2.42	100	✓ Acetec
LISINOPRIL			
* Tab 5 mg	11.07	90	✓ Ethics Lisinopril
* Tab 10 mg	11.67	90	✓ Ethics Lisinopril
* Tab 20 mg	14.69	90	✓ Ethics Lisinopril
PERINDOPRIL			
Tab 2 mg	1.58	30	✓ Coversyl
Tab 4 mg	2.95	30	✓ Coversyl
QUINAPRIL			
Tab 5 mg	5.97	90	✓ Arrow-Quinapril 5
Tab 10 mg	5.18	90	✓ Arrow-Quinapril 10
Tab 20 mg	7.95	90	✓ Arrow-Quinapril 20

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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ACE Inhibitors with Diuretics

QUINAPRIL WITH HYDROCHLOROTHIAZIDE – Subsidy by endorsement

Subsidy by endorsement – Subsidised for patients who were taking quinapril with hydrochlorothiazide prior to 1 May 2022 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of quinapril with hydrochlorothiazide.

Tab 10 mg with hydrochlorothiazide 12.5 mg.....	4.10	30	✓ Accuretic 10
Tab 20 mg with hydrochlorothiazide 12.5 mg.....	5.25	30	✓ Accuretic 20

Angiotensin II Antagonists

CANDESARTAN CILEXETIL

* Tab 4 mg	2.00	90	✓ Candestar
* Tab 8 mg	2.28	90	✓ Candestar
* Tab 16 mg	3.31	90	✓ Candestar
* Tab 32 mg	5.26	90	✓ Candestar

LOSARTAN POTASSIUM

Tab 12.5 mg	1.56	84	✓ Losartan Actavis
Tab 25 mg	1.84	84	✓ Losartan Actavis
Tab 50 mg	2.25	84	✓ Losartan Actavis
Tab 100 mg	3.50	84	✓ Losartan Actavis

Angiotensin II Antagonists with Diuretics

LOSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE

Tab 50 mg with hydrochlorothiazide 12.5 mg.....	4.00	30	✓ Arrow-Losartan & Hydrochlorothiazide
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Angiotensin II Antagonists with Neprilysin Inhibitors

SACUBITRIL WITH VALSARTAN – Special Authority see [SA1905 below](#) – Retail pharmacy

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

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

► [SA1905](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

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.

Renewal from any relevant practitioner. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Subsidy
(Manufacturer's Price)
\$

Fully
Subsidised
Per ✓

Brand or
Generic
Manufacturer

Antiarrhythmics

For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaesthetics, Local, [page 118](#)

AMIODARONE HYDROCHLORIDE

▲ Tab 100 mg	3.49	30	✓ Aratac
Aratac to be Principal Supply on 1 December 2022			
▲ Tab 200 mg	4.49	30	✓ Aratac
Aratac to be Principal Supply on 1 December 2022			
Inj 50 mg per ml, 3 ml ampoule – Up to 10 inj available on a PSO	15.22	10	✓ Max Health
Max Health to be Principal Supply on 1 December 2022			

ATROPINE SULPHATE

* Inj 600 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	15.09	10	✓ Martindale
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DIGOXIN

* Tab 62.5 mcg – Up to 30 tab available on a PSO	7.80	240	✓ Lanoxin PG
* Tab 250 mcg – Up to 30 tab available on a PSO	16.90	240	✓ Lanoxin
* Oral liq 50 mcg per ml	16.60	60 ml	✓ Lanoxin
			✓ Lanoxin Paediatric
			Elixir ^{\$29}
			✓ Lanoxin S29 ^{\$29}

DISOPYRAMIDE PHOSPHATE

▲ Cap 100 mg	23.87	100	✓ Rythmodan
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FLECAINIDE ACETATE

▲ Tab 50 mg	19.95	60	✓ Flecainide BNM
▲ Cap long-acting 100 mg	39.51	90	✓ Flecainide
			Controlled Release Teva
▲ Cap long-acting 200 mg	61.06	90	✓ Flecainide
			Controlled Release Teva
Inj 10 mg per ml, 15 ml ampoule	100.00	5	✓ Tambacor

MEXILETINE HYDROCHLORIDE

▲ Cap 150 mg	162.00	100	✓ Teva ^{\$29}
▲ Cap 250 mg	202.00	100	✓ Teva ^{\$29}

PROPAFENONE HYDROCHLORIDE

▲ Tab 150 mg	40.90	50	✓ Rytmonorm
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Antihypotensives

MIDODRINE – Special Authority see [SA1474 below](#) – Retail pharmacy

Tab 2.5 mg	53.00	100	✓ Gutron
Tab 5 mg	79.00	100	✓ Gutron

➔ [SA1474](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years where patient has disabling orthostatic hypotension not due to drugs.

continued...

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

Note: Treatment should be started with small doses and titrated upwards as necessary. Hypertension should be avoided, and the usual target is a standing systolic blood pressure of 90 mm Hg.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Beta-Adrenoceptor Blockers

Beta Adrenoceptor Blockers

ATENOLOL

* Tab 50 mg	9.33	500	✓ <u>Mylan Atenolol</u>
* Tab 100 mg	14.20	500	✓ <u>Mylan Atenolol</u>
* Oral liq 25 mg per 5 ml	21.25	300 ml OP	✓ <u>Atenolol AFT</u>
			S29 ^{S29}
	38.20		✓ <u>Essential</u>
			Generics ^{S29}
	49.85		✓ <u>Atenolol AFT</u>

Restricted to children under 12 years of age.

BISOPROLOL FUMARATE

* Tab 2.5 mg	1.84	90	✓ <u>Bisoprolol Mylan</u>
* Tab 5 mg	2.55	90	✓ <u>Bisoprolol Mylan</u>
* Tab 10 mg	3.62	90	✓ <u>Bisoprolol Mylan</u>

CARVEDILOL

* Tab 6.25 mg	2.24	60	✓ <u>Carvedilol Sandoz</u>
* Tab 12.5 mg	2.30	60	✓ <u>Carvedilol Sandoz</u>
* Tab 25 mg	2.95	60	✓ <u>Carvedilol Sandoz</u>

LABETALOL

* Tab 100 mg	14.50	100	✓ <u>Trandate</u>
* Tab 200 mg	27.00	100	✓ <u>Trandate</u>
* Inj 5 mg per ml, 20 ml ampoule	59.06	5	Trandate
	(88.60)		
* inj 5 mg per ml, 20 ml vial	42.29	1	Alvogen ^{S29}
	(48.20)		

METOPROLOL SUCCINATE

* Tab long-acting 23.75 mg	1.45	30	✓ <u>Betaloc CR</u>
* Tab long-acting 47.5 mg	1.43	30	✓ <u>Betaloc CR</u>
* Tab long-acting 95 mg	2.15	30	✓ <u>Betaloc CR</u>
* Tab long-acting 190 mg	4.27	30	✓ <u>Betaloc CR</u>

METOPROLOL TARTRATE

Tab 50 mg	5.66	100	✓ <u>IPCA-Metoprolol</u>
Tab 100 mg	7.55	60	✓ <u>IPCA-Metoprolol</u>
* Tab long-acting 200 mg	23.40	28	✓ <u>Slow-Lopresor</u>
* Inj 1 mg per ml, 5 ml vial	26.50	5	✓ <u>Metoprolol IV Mylan</u>

NADOLOL

Tab 40 mg	19.19	100	✓ <u>Nadolol BNM</u> ^{S29}
Tab 80 mg	30.39	100	✓ <u>Nadolol BNM</u> ^{S29}

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PROPRANOLOL				
Tab 10 mg	7.04	100	✓	Drofate
Tab 40 mg	8.75	100	✓	IPCA-Propranolol
* Cap long-acting 160 mg	18.17	100	✓	Cardinol LA
* Oral liq 4 mg per ml – Special Authority see SA1327 below –				
Retail pharmacy.....	CBS	500 ml	✓	Roxane-Propranolol <small>S29</small>

➤ **SA1327 Special Authority for Subsidy**

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 For the treatment of a child under 12 years with an haemangioma causing functional impairment (not for cosmetic reasons only); or
- 2 For the treatment of a child under 12 years with cardiac arrhythmias or congenital cardiac abnormalities.

Renewal from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 For the treatment of a child under 12 years with an haemangioma causing functional impairment (not for cosmetic reasons only); or
- 2 For the treatment of a child under 12 years with cardiac arrhythmias or congenital cardiac abnormalities.

SOTALOL

* Tab 80 mg	37.50	500	✓	Mylan
* Tab 160 mg	14.00	100	✓	Mylan

Calcium Channel Blockers

Dihydropyridine Calcium Channel Blockers

AMLODIPINE

* Tab 2.5 mg	1.08	90	✓	Vasorex
* Tab 5 mg	0.96	90	✓	Vasorex
* Tab 10 mg	1.19	90	✓	Vasorex

FELODIPINE

* Tab long-acting 2.5 mg	1.45	30	✓	Plendil ER
* Tab long-acting 5 mg	4.07	90	✓	Felo 5 ER
* Tab long-acting 10 mg	4.32	90	✓	Felo 10 ER

NIFEDIPINE

* Tab long-acting 10 mg	18.80	56	✓	Tensipine MR10 <small>S29</small>
* Tab long-acting 20 mg	9.12	50	✓	Mylan (12 hr release) <small>S29</small>
	17.72	100	✓	Nyefax Retard
* Tab long-acting 30 mg	4.78	14	✓	Mylan Italy (24 hr release) <small>S29</small>
	34.10	100	✓	Mylan (24 hr release) <small>S29</small>
* Tab long-acting 60 mg	52.81	100	✓	Mylan (24 hr release) <small>S29</small>

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Other Calcium Channel Blockers				
DILTIAZEM HYDROCHLORIDE				
Cap extended-release 120 mg	44.40	100	✓	Accord ^{S29}
* Cap long-acting 120 mg	33.42	500	✓	Apo-Diltiazem CD
* Cap long-acting 180 mg	7.00	30	✓	Cardizem CD
* Cap long-acting 240 mg	9.30	30	✓	Cardizem CD
PERHEXILINE MALEATE				
* Tab 100 mg	62.90	100	✓	Pexsig
VERAPAMIL HYDROCHLORIDE				
* Tab 40 mg	7.01	100	✓	Isoptin
* Tab 80 mg	11.74	100	✓	Isoptin
* Tab long-acting 120 mg	36.02	100	✓	Isoptin Retard ^{S29}
			✓	Isoptin SR
			✓	Isoptin SR
* Tab long-acting 240 mg	15.12	30		
* Inj 2.5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	25.00	5	✓	Isoptin
Centrally-Acting Agents				
CLONIDINE				
* Patch 2.5 mg, 100 mcg per day – Only on a prescription	10.34	4	✓	Mylan
* Patch 5 mg, 200 mcg per day – Only on a prescription	13.18	4	✓	Mylan
* Patch 7.5 mg, 300 mcg per day – Only on a prescription	16.93	4	✓	Mylan
CLONIDINE HYDROCHLORIDE				
* Tab 25 mcg	8.75	112	✓	Clonidine BNM
	29.32		✓	Clonidine Teva
* Tab 150 mcg	37.07	100	✓	Catapres
* Inj 150 mcg per ml, 1 ml ampoule	29.68	10	✓	Medsurge
<i>(Clonidine BNM Tab 25 mcg to be delisted 1 November 2022)</i>				
METHYLDOPA				
* Tab 250 mg	15.10	100	✓	Methyldopa Mylan
	52.85	500	✓	Methyldopa Mylan S29 ^{S29}

Diuretics

Loop Diuretics

BUMETANIDE				
* Tab 1 mg	4.91	30	✓	Burinex S29 ^{S29}
	16.36	100	✓	Burinex
* Inj 500 mcg per ml, 4 ml vial	7.95	5	✓	Burinex

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FUROSEMIDE [FRUSEMIDE]				
Tab 40 mg – Up to 30 tab available on a PSO	8.00	1,000	✓	IPCA-Frusemide
* Tab 500 mg	25.00	50	✓	Urex Forte
	89.48		✓	Furosemid- Ratiopharm S29
	169.96	100	✓	Furosemid- Ratiopharm S29
* Oral liq 10 mg per ml	11.20	30 ml OP	✓	Lasix
* Inj 10 mg per ml, 25 ml ampoule	60.65	6	✓	Lasix
* Inj 10 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	2.40	5	✓	Furosemide-Baxter

Potassium Sparing Diuretics

AMILORIDE HYDROCHLORIDE				
Oral liq 1 mg per ml	32.10	25 ml OP	✓	Biomed
EPLERENONE – Special Authority see SA1728 below – Retail pharmacy				
Tab 25 mg	18.50	30	✓	Inspira
Tab 50 mg	25.00	30	✓	Inspira

►SA1728 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Patient has heart failure with ejection fraction less than 40%; and
- 2 Either:
 - 2.1 Patient is intolerant to optimal dosing of spironolactone; or
 - 2.2 Patient has experienced a clinically significant adverse effect while on optimal dosing of spironolactone.

METOLAZONE				
Tab 5 mg	CBS	1	✓	Metolazone S29
		50	✓	Zaroxolyn S29
SPIRONOLACTONE				
* Tab 25 mg	3.68	100	✓	Spiractin
* Tab 100 mg	10.65	100	✓	Spiractin
Oral liq 5 mg per ml	30.60	25 ml OP	✓	Biomed

Potassium Sparing Combination Diuretics

AMILORIDE HYDROCHLORIDE WITH FUROSEMIDE				
* Tab 5 mg with furosemide 40 mg	8.63	28	✓	Frumil
AMILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIAZIDE				
* Tab 5 mg with hydrochlorothiazide 50 mg	5.00	50	✓	Moduretic

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Thiazide and Related Diuretics				
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]				
* Tab 2.5 mg – Up to 150 tab available on a PSO	20.00	500	✓	<u>Arrow-</u> <u>Bendrofluazide</u>
May be supplied on a PSO for reasons other than emergency.				
* Tab 5 mg	34.55	500	✓	<u>Arrow-</u> <u>Bendrofluazide</u>
CHLOROTHIAZIDE				
Oral liq 50 mg per ml	27.82	25 ml OP	✓	<u>Biomed</u>
CHLORTALIDONE [CHLORTHALIDONE]				
Tab 25 mg	3.90	30	✓	<u>Igrotan</u> ^{\$29}
	6.50	50	✓	<u>Hygroton</u>
INDAPAMIDE				
* Tab 2.5 mg	10.45	90	✓	<u>Dapa-Tabs</u>
	11.61	100	✓	<u>Mylan</u> <u>Indapamide</u> ^{\$29}

Lipid-Modifying Agents

Fibrates

BEZAFIBRATE				
* Tab 200 mg	19.46	90	✓	<u>Bezalip</u>
* Tab long-acting 400 mg	21.21	30	✓	<u>Bezalip Retard</u>

Other Lipid-Modifying Agents

ACIPIMOX				
* Cap 250 mg	21.56	30	✓	<u>Olbetam</u>
			✓	<u>Olbetam</u> ^{\$29} ^{\$29}

Resins

COLESTIPOL HYDROCHLORIDE				
Grans for oral liq 5 g	32.89	30	✓	<u>Colestid</u>

HMG CoA Reductase Inhibitors (Statins)

ATORVASTATIN				
* Tab 10 mg	6.16	500	✓	<u>Lorstat</u>
* Tab 20 mg	9.24	500	✓	<u>Lorstat</u>
* Tab 40 mg	14.92	500	✓	<u>Lorstat</u>
* Tab 80 mg	26.54	500	✓	<u>Lorstat</u>
PRAVASTATIN				
* Tab 20 mg	2.11	28	✓	<u>Pravastatin Mylan</u>
* Tab 40 mg	3.61	28	✓	<u>Pravastatin Mylan</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ROSUVASTATIN – Special Authority see SA2093 below – Retail pharmacy				
* Tab 5 mg	1.70	30	✓	Rosuvastatin Viatris
* Tab 10 mg	2.42	30	✓	Rosuvastatin Viatris
* Tab 20 mg	3.92	30	✓	Rosuvastatin Viatris
* Tab 40 mg	5.28	30	✓	Rosuvastatin Viatris

➔ **SA2093** **Special Authority for Subsidy**

Initial application — (cardiovascular disease risk) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

1 Both:

- 1.1 Patient is considered to be at risk of cardiovascular disease; and
- 1.2 Patient is Māori or any Pacific ethnicity; or

2 Both:

- 2.1 Patient has a calculated risk of cardiovascular disease of at least 15% over 5 years; and
- 2.2 LDL cholesterol has not reduced to less than 1.8 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin.

Initial application — (familial hypercholesterolemia) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Patient has familial hypercholesterolemia (defined as a Dutch Lipid Criteria score greater than or equal to 6); and
- 2 LDL cholesterol has not reduced to less than 1.8 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin.

Initial application — (established cardiovascular disease) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 Patient has proven coronary artery disease (CAD); or
 - 1.2 Patient has proven peripheral artery disease (PAD); or
 - 1.3 Patient has experienced an ischaemic stroke; and
- 2 LDL cholesterol has not reduced to less than 1.4 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin.

Initial application — (recurrent major cardiovascular events) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Patient has experienced a recurrent major cardiovascular event (defined as myocardial infarction, ischaemic stroke, coronary revascularisation, hospitalisation for unstable angina) in the last 2 years; and
- 2 LDL cholesterol has not reduced to less than 1.0 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin.

SIMVASTATIN

* Tab 10 mg	1.23	90	✓	Simvastatin Mylan
* Tab 20 mg	2.03	90	✓	Simvastatin Mylan
* Tab 40 mg	3.58	90	✓	Simvastatin Mylan
* Tab 80 mg	7.12	90	✓	Simvastatin Mylan

Selective Cholesterol Absorption Inhibitors

EZETIMIBE – Special Authority see [SA1045 on the next page](#) – Retail pharmacy

* Tab 10 mg	1.95	30	✓	Ezetimibe Sandoz
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1045 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:

- 1 Patient has a calculated absolute risk of cardiovascular disease of at least 15% over 5 years; and
- 2 Patient's LDL cholesterol is 2.0 mmol/litre or greater; and
- 3 Any of the following:
 - 3.1 The patient has rhabdomyolysis (defined as muscle aches and creatine kinase more than 10 × normal) when treated with one statin; or
 - 3.2 The patient is intolerant to both simvastatin and atorvastatin; or
 - 3.3 The patient has not reduced their LDL cholesterol to less than 2.0 mmol/litre with the use of the maximal tolerated dose of atorvastatin.

Notes: A patient who has failed to reduce their LDL cholesterol to < 2.0 mmol/litre with the use of a less potent statin should use a more potent statin prior to consideration being given to the use of non-statin therapies.

Other treatment options including fibrates, resins and nicotinic acid should be considered after failure of statin therapy.

If a patient's LDL cholesterol cannot be calculated because the triglyceride level is too high then a repeat test should be performed and if the LDL cholesterol again cannot be calculated then it can be considered that the LDL cholesterol is greater than 2.0 mmol/litre.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

EZETIMIBE WITH SIMVASTATIN – Special Authority see SA1046 below – Retail pharmacy

Tab 10 mg with simvastatin 10 mg	5.15	30	✓ Zimybe
Tab 10 mg with simvastatin 20 mg	6.15	30	✓ Zimybe
Tab 10 mg with simvastatin 40 mg	7.15	30	✓ Zimybe
Tab 10 mg with simvastatin 80 mg	8.15	30	✓ Zimybe

►SA1046 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:

- 1 Patient has a calculated absolute risk of cardiovascular disease of at least 15% over 5 year; and
- 2 Patient's LDL cholesterol is 2.0 mmol/litre or greater; and
- 3 The patient has not reduced their LDL cholesterol to less than 2.0 mmol/litre with the use of the maximal tolerated dose of atorvastatin.

Notes: A patient who has failed to reduce their LDL cholesterol to less than or equal to 2.0 mmol/litre with the use of a less potent statin should use a more potent statin prior to consideration being given to the use of non-statin therapies.

Other treatment options including fibrates, resins and nicotinic acid should be considered after failure of statin therapy.

If a patient's LDL cholesterol cannot be calculated because the triglyceride level is too high then a repeat test should be performed and if the LDL cholesterol again cannot be calculated then it can be considered that the LDL cholesterol is greater than 2.0 mmol/litre.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Nitrates

GLYCERYL TRINITRATE

* Oral pump spray, 400 mcg per dose – Up to 250 dose available on a PSO	6.09	250 dose OP	✓ Nitrolingual Pump Spray
* Patch 25 mg, 5 mg per day	15.73	30	✓ Nitroderm TTS
* Patch 50 mg, 10 mg per day	18.62	30	✓ Nitroderm TTS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ISOSORBIDE MONONITRATE				
* Tab 20 mg	19.55	100	✓	Ismo 20
* Tab long-acting 40 mg.....	8.20	30	✓	Ismo 40 Retard
* Tab long-acting 60 mg.....	9.25	90	✓	Duride

Sympathomimetics

ADRENALINE

Inj 1 in 1,000, 1 ml ampoule – Up to 5 inj available on a PSO	4.98	5	✓	Aspen Adrenaline
	10.76		✓	DBL Adrenaline
Inj 1 in 10,000, 10 ml ampoule – Up to 5 inj available on a PSO	27.00	5	✓	Hospira
	49.00	10	✓	Aspen Adrenaline

Vasodilators

HYDRALAZINE HYDROCHLORIDE

* Tab 25 mg – Special Authority see SA1321 below – Retail pharmacy.....	CBS	1	✓	Hydralazine
		56	✓	Onelink ^{S29}
		84	✓	AMDIPHARM ^{S29}
		100	✓	Onelink ^{S29}
* Inj 20 mg ampoule	25.90	5	✓	Apresoline

►SA1321 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 For the treatment of refractory hypertension; or
- 2 For the treatment of heart failure in combination with a nitrate, in patients who are intolerant or have not responded to ACE inhibitors and/or angiotensin receptor blockers.

MINOXIDIL

▲ Tab 10 mg	70.00	100	✓	Loniten
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NICORANDIL

▲ Tab 10 mg	25.57	60	✓	Ikorel
▲ Tab 20 mg	32.28	60	✓	Ikorel

PAPAVERINE HYDROCHLORIDE

* Inj 12 mg per ml, 10 ml ampoule	257.12	5	✓	Hospira
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PENTOXIFYLLINE [OXPENTIFYLLINE]

Tab 400 mg	42.26	50	✓	Trental 400
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Endothelin Receptor Antagonists

AMBRISENTAN – Special Authority see [SA1702 on the next page](#) – Retail pharmacy

Tab 5 mg	1,550.00	30	✓	Ambrisentan Mylan
Tab 10 mg	1,550.00	30	✓	Ambrisentan Mylan
			✓	Mylan

(Ambrisentan Mylan Tab 10 mg to be delisted 1 March 2023)

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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►SA1702 Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

Notes: Application details may be obtained from Pharmac's website [schedule.pharmac.govt.nz/SAForms](https://www.pharmac.govt.nz/SAForms) or:

The Coordinator, PAH Panel

Pharmac, PO Box 10-254, WELLINGTON

Tel: (04) 916 7561, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz

BOSENTAN – Special Authority see SA1991 below – Retail pharmacy

Tab 62.5 mg	119.85	60	✓ Bosentan Dr Reddy's
Tab 125 mg	119.85	60	✓ Bosentan Dr Reddy's

►SA1991 Special Authority for Subsidy

Initial application only from a respiratory specialist, cardiologist or medical practitioner on the recommendation of a respiratory physician or cardiologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)*; and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice) clinical classifications; and
- 3 PAH is at NYHA/WHO functional class II, III, or IV; and
- 4 Any of the following:
 - 4.1 Both:
 - 4.1.1 Bosentan is to be used as PAH monotherapy; and
 - 4.1.2 Either:
 - 4.1.2.1 Patient is intolerant or contraindicated to sildenafil; or
 - 4.1.2.2 Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease; or
 - 4.2 Both:
 - 4.2.1 Bosentan is to be used as PAH dual therapy; and
 - 4.2.2 Either:
 - 4.2.2.1 Patient has tried a PAH monotherapy for at least three months and failed to respond; or
 - 4.2.2.2 Patient deteriorated while on a PAH monotherapy; or
 - 4.3 Both:
 - 4.3.1 Bosentan is to be used as PAH triple therapy; and
 - 4.3.2 Any of the following:
 - 4.3.2.1 Patient is on the lung transplant list; or
 - 4.3.2.2 Patient is presenting acutely with idiopathic pulmonary arterial hypertension (IPAH) in New York Heart Association/World Health Organization (NYHA/WHO) Functional Class IV; or
 - 4.3.2.3 Patient is deteriorating rapidly to NYHA/WHO Functional Class IV who may be lung transplant recipients in the future, if their disease is stabilised; or
 - 4.3.2.4 Patient has PAH associated with the scleroderma spectrum of diseases (APAHSSD) who have no major morbidities and are deteriorating despite combination therapy.

Renewal only from a respiratory specialist, cardiologist or medical practitioner on the recommendation of a respiratory physician or cardiologist. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 Both:
 - 1.1 Bosentan is to be used as PAH monotherapy; and
 - 1.2 Patient is stable or has improved while on bosentan; or
- 2 Both:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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continued...

- 2.1 Bosentan is to be used as PAH dual therapy; and
- 2.2 Patient has tried a PAH monotherapy for at least three months and either failed to respond or later deteriorated; or
- 3 Both:
 - 3.1 Bosentan is to be used as PAH triple therapy; and
 - 3.2 Any of the following:
 - 3.2.1 Patient is on the lung transplant list; or
 - 3.2.2 Patient is presenting acutely with idiopathic pulmonary arterial hypertension (IPAH) in New York Heart Association/World Health Organization (NYHA/WHO) Functional Class IV; or
 - 3.2.3 Patient is deteriorating rapidly to NYHA/WHO Functional Class IV who may be lung transplant recipients in the future, if their disease is stabilised; or
 - 3.2.4 Patient has PAH associated with the scleroderma spectrum of diseases (APAHSSD) who have no major morbidities and are deteriorating despite combination therapy.

Phosphodiesterase Type 5 Inhibitors

SILDENAFIL – Special Authority see SA1992 below – Retail pharmacy

Tab 25 mg	0.85	4	✓ <u>Vedafil</u>
Tab 50 mg	1.70	4	✓ <u>Vedafil</u>
Tab 100 mg	10.20	12	✓ <u>Vedafil</u>

SA1992 Special Authority for Subsidy

Initial application — (Raynaud's Phenomenon*) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 Patient has Raynaud's Phenomenon*; and
- 2 Patient has severe digital ischaemia (defined as severe pain requiring hospital admission or with a high likelihood of digital ulceration; digital ulcers; or gangrene); and
- 3 Patient is following lifestyle management (avoidance of cold exposure, sufficient protection, smoking cessation support, avoidance of sympathomimetic drugs); and
- 4 Patient is being treated with calcium channel blockers and nitrates (or these are contraindicated/not tolerated).

Initial application — (Pulmonary arterial hypertension*) only from a respiratory specialist, cardiologist or medical practitioner on the recommendation of a respiratory specialist or cardiologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)*; and
- 2 Any of the following:
 - 2.1 PAH is in Group 1 of the WHO (Venice) clinical classifications; or
 - 2.2 PAH is in Group 4 of the WHO (Venice) clinical classifications; or
 - 2.3 PAH is in Group 5 of the WHO (Venice) clinical classifications; and
- 3 Any of the following:
 - 3.1 PAH is in NYHA/WHO functional class II; or
 - 3.2 PAH is in NYHA/WHO functional class III; or
 - 3.3 PAH is in NYHA/WHO functional class IV; and
- 4 Either:
 - 4.1 All of the following:
 - 4.1.1 Patient has a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.2 Either:
 - 4.1.2.1 Patient has a mean pulmonary artery pressure (PAPm) > 25 mmHg; or

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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continued...

4.1.2.2 Patient is peri Fontan repair; and

4.1.3 Patient has a pulmonary vascular resistance (PVR) of at least 3 Wood Units or at least 240 International Units (dyn s cm⁻⁵); or

4.2 Testing for PCWP, PAPm, or PVR cannot be performed due to the patient's young age.

Note: Indications marked with * are unapproved indications.

Initial application — (erectile dysfunction due to spinal cord injury) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has a documented history of traumatic or non-traumatic spinal cord injury; and
- 2 Patient has erectile dysfunction secondary to spinal cord injury requiring pharmacological treatment.

Renewal — (erectile dysfunction due to spinal cord injury) from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Prostacyclin Analogues

EPOPROSTENOL – Special Authority see [SA1696 below](#) – Retail pharmacy

Inj 500 mcg vial.....	36.61	1	✓ Velettri
Inj 1.5 mg vial	73.21	1	✓ Velettri

► [SA1696](#) Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

Notes: Application details may be obtained from Pharmac's website schedule.pharmac.govt.nz/SAForms or:
The Coordinator, PAH Panel

Pharmac, PO Box 10-254, WELLINGTON

Tel: (04) 916 7561, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz

ILOPROST – Special Authority see [SA1705 below](#) – Retail pharmacy

Nebuliser soln 10 mcg per ml, 2 ml	740.10	30	✓ Ventavis
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► [SA1705](#) Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

Notes: Application details may be obtained from Pharmac's website schedule.pharmac.govt.nz/SAForms or:
The Coordinator, PAH Panel

Pharmac, PO Box 10-254, WELLINGTON

Tel: (04) 916 7561, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Antiacne Preparations

For systemic antibacterials, refer to INFECTIONS, Antibacterials, [page 89](#)

ADAPALENE

- Maximum of 30 g per prescription
- Only on a prescription

Crm 0.1%.....	22.89	30 g OP	✓ Differin
Gel 0.1%.....	22.89	30 g OP	✓ Differin

ISOTRETINOIN – Special Authority see [SA2023 below](#) – Retail pharmacy

Cap 5 mg.....	11.26	60	✓ Oratane
Cap 10 mg.....	18.75	120	✓ Oratane
Cap 20 mg.....	26.73	120	✓ Oratane

►SA2023 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- Applicant has an up to date knowledge of the safety issues around isotretinoin and is competent to prescribe isotretinoin; and
- Either:
 - Patient is of child bearing potential and the possibility of pregnancy has been excluded prior to commencement of treatment and patient has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and that they must not become pregnant during treatment and for a period of one month after the completion of treatment; or
 - Patient is not of child bearing potential.

Note: Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

Renewal from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Either:

- Patient is of child bearing potential and the possibility of pregnancy has been excluded prior to commencement of treatment and patient has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and that they must not become pregnant during treatment and for a period of one month after the completion of treatment; or
- Patient is not of child bearing potential.

Note: Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

TRETINOIN

Crm 0.5 mg per g – Maximum of 50 g per prescription	15.57	50 g OP	✓ ReTrieve
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Antibacterials Topical

For systemic antibacterials, refer to INFECTIONS, Antibacterials, [page 89](#)

HYDROGEN PEROXIDE

* Crm 1%.....	8.56	10 g OP	✓ Crystaderm
		15 g OP	✓ Crystaderm

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
MUPIROCI				
Oint 2%.....	6.60 (11.50)	15 g OP		Bactroban
a) Only on a prescription				
b) Not in combination				
SODIUM FUSIDATE [FUSIDIC ACID]				
Crm 2%.....	1.59	5 g OP	✓ Foban	
a) Maximum of 5 g per prescription				
b) Only on a prescription				
c) Not in combination				
Oint 2%.....	1.59	5 g OP	✓ Foban	
a) Maximum of 5 g per prescription				
b) Only on a prescription				
c) Not in combination				
SULFADIAZINE SILVER				
Crm 1%.....	10.80	50 g OP	✓ Flamazine	
a) Up to 250 g available on a PSO				
b) Not in combination				

Antifungals Topical

For systemic antifungals, refer to INFECTIONS, Antifungals, [page 96](#)

AMOROLFINE

- a) Only on a prescription
- b) Not in combination

Nail soln 5%.....	14.93	5 ml OP	✓ MycoNail
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CLOTRIMAZOLE

* Crm 1%.....	0.77	20 g OP	✓ Clomazol
a) Only on a prescription			
b) Not in combination			
* Soln 1%.....	4.36 (7.55)	20 ml OP	Canesten
a) Only on a prescription			
b) Not in combination			

ECONAZOLE NITRATE

Crm 1%.....	1.00 (7.48)	20 g OP	Pevaryl
a) Only on a prescription			
b) Not in combination			
Foaming soln 1%, 10 ml sachets.....	9.89 (17.23)	3	Pevaryl
a) Only on a prescription			
b) Not in combination			

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
MICONAZOLE NITRATE				
* Crm 2%.....	0.81	15 g OP	✓	Multichem
a) Only on a prescription				
b) Not in combination				
* Lotn 2%	4.36 (10.03)	30 ml OP		Daktarin
a) Only on a prescription				
b) Not in combination				
* Tinct 2%.....	4.36 (12.10)	30 ml OP		Daktarin
a) Only on a prescription				
b) Not in combination				

Antipruritic Preparations

CALAMINE

- a) Only on a prescription
- b) Not in combination

Crm, aqueous, BP 1.08 100 g ✓ **Calamine-AFT**

CROTAMITON

- a) Only on a prescription
- b) Not in combination

Crm 10%..... 3.29 20 g OP ✓ **Itch-Soothe**

MENTHOL – Only in combination

- 1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain
- 2) With or without other dermatological galenicals.

Crystals..... 6.92 25 g ✓ **MidWest**
29.60 100 g ✓ **MidWest**

Corticosteroids Topical

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, [page 79](#)

Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE

Crm 0.05%..... 2.96 15 g OP ✓ **Diprosone**
36.00 50 g OP ✓ **Diprosone**
Oint 0.05%..... 2.96 15 g OP ✓ **Diprosone**
36.00 50 g OP ✓ **Diprosone**
Oint 0.05% in propylene glycol base 4.33 30 g OP ✓ **Diprosone OV**

BETAMETHASONE VALERATE

* Crm 0.1%..... 4.53 50 g OP ✓ **Beta Cream**
* Oint 0.1%..... 5.84 50 g OP ✓ **Beta Ointment**
* Lotn 0.1% 25.00 50 ml OP ✓ **Betnovate**

CLOBETASOL PROPIONATE

* Crm 0.05%..... 2.40 30 g OP ✓ **Dermol**
* Oint 0.05%..... 2.33 30 g OP ✓ **Dermol**

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CLOBETASONE BUTYRATE				
Crn 0.05%.....	5.38 (10.00)	30 g OP		Eumovate
HYDROCORTISONE				
* Crn 1% – Only on a prescription.....	3.70	100 g OP	✓	Hydrocortisone (PSM)
	17.15	500 g	✓	Hydrocortisone (PSM)
* Powder – Only in combination.....	49.95	25 g	✓	ABM
Up to 5% in a dermatological base (not proprietary Topical Corticosteroid – Plain) with or without other dermatological galenicals				
HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN				
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% – Only on a prescription	10.57	250 ml	✓	DP Lotn HC
HYDROCORTISONE BUTYRATE				
Lipocream 0.1%.....	4.85	100 g OP	✓	Locoid Lipocream
Oint 0.1%.....	10.28	100 g OP	✓	Locoid
Milky emul 0.1%	12.33	100 ml OP	✓	Locoid Crelo
METHYLPREDNISOLONE ACEPONATE				
Crn 0.1%.....	4.46	15 g OP	✓	Advantan
Oint 0.1%.....	4.46	15 g OP	✓	Advantan
MOMETASONE FUROATE				
Crn 0.1%.....	1.95	15 g OP	✓	Elocon Alcohol Free
	3.10	50 g OP	✓	Elocon Alcohol Free
Oint 0.1%.....	1.95	15 g OP	✓	Elocon
	2.90	50 g OP	✓	Elocon
Lotn 0.1%	4.50	30 ml OP	✓	Elocon
TRIAMCINOLONE ACETONIDE				
Crn 0.02%.....	6.30	100 g OP	✓	Aristocort
Oint 0.02%.....	6.35	100 g OP	✓	Aristocort
Corticosteroids - Combination				
BETAMETHASONE VALERATE WITH SODIUM FUSIDATE [FUSIDIC ACID]				
Crn 0.1% with sodium fusidate (fusidic acid) 2%.....	3.49 (10.45)	15 g OP		Fucicort
a) Maximum of 15 g per prescription				
b) Only on a prescription				
HYDROCORTISONE WITH MICONAZOLE – Only on a prescription				
* Crn 1% with miconazole nitrate 2%.....	1.89	15 g OP	✓	Micreme H
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN – Only on a prescription				
Crn 1% with natamycin 1% and neomycin sulphate 0.5%	3.35	15 g OP	✓	Pimafucort
Oint 1% with natamycin 1% and neomycin sulphate 0.5%.....	3.35	15 g OP	✓	Pimafucort
<i>(Pimafucort Crn 1% with natamycin 1% and neomycin sulphate 0.5% to be delisted 1 April 2023)</i>				
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN				
Crn 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g – Only on a prescription	3.49 (9.28)	15 g OP		Viaderm KC

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
Barrier Creams and Emollients			
Barrier Creams			
DIMETHICONE			
* Crm 5% pump bottle.....	4.30	500 ml OP	✓ healthE Dimethicone 5%
healthE Dimethicone 5% to be Principal Supply on 1 December 2022			
* Crm 10% pump bottle.....	4.52	500 ml OP	✓ healthE Dimethicone 10%
ZINC AND CASTOR OIL			
* Oint.....	4.65	500 g	✓ Boucher
Emollients			
AQUEOUS CREAM			
* Crm.....	1.73	500 g	✓ Boucher ✓ <u>GEM Aqueous Cream</u>
<i>(Boucher Crm to be delisted 1 October 2022)</i>			
CETOMACROGOL			
* Crm BP.....	1.99	500 g	✓ <u>Cetomacrogol-AFT</u>
CETOMACROGOL WITH GLYCEROL			
Crm 90% with glycerol 10%.....	2.35	500 ml OP	✓ Boucher ✓ Evara ✓ Pharmacy Health Sorbolene with Glycerin
	3.10	1,000 ml OP	✓ Boucher ✓ Evara
<i>(Boucher Crm 90% with glycerol 10% to be delisted 1 March 2023)</i>			
<i>(Boucher Crm 90% with glycerol 10% to be delisted 1 March 2023)</i>			
EMULSIFYING OINTMENT			
* Oint BP.....	3.40	500 g	✓ <u>Emulsifying Ointment ADE</u>
OIL IN WATER EMULSION			
* Crm.....	2.04	500 g	✓ <u>Fatty Cream AFT</u>
PARAFFIN			
Oint liquid paraffin 50% with white soft paraffin 50%.....	5.35	500 ml OP	✓ healthE
UREA			
* Crm 10%.....	1.37	100 g OP	✓ healthE Urea Cream

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
WOOL FAT WITH MINERAL OIL – Only on a prescription				
* Lotn hydraous 3% with mineral oil.....	5.60	1,000 ml		
	(11.95)			DP Lotion
	1.40	250 ml OP		
	(4.53)			DP Lotion
	5.60	1,000 ml		
	(20.53)			Alpha-Keri Lotion
	(23.91)			BK Lotion
	1.40	250 ml OP		
	(7.73)			BK Lotion

Other Dermatological Bases

PARAFFIN

White soft – Only in combination.....	4.99	450 g	✓ healthE
	19.99	2,500 g	✓ healthE

Only in combination with a dermatological galenical or as a diluent for a proprietary Topical Corticosteroid – Plain.

Minor Skin Infections

POVIDONE IODINE

Oint 10%.....	7.40	65 g OP	✓ Betadine
a) Maximum of 130 g per prescription			
b) Only on a prescription			
Antiseptic Solution 10%.....	4.15	100 ml	✓ Riodine
Antiseptic soln 10%.....	3.83	15 ml	✓ Riodine
	5.40	500 ml	✓ Riodine
Skin preparation, povidone iodine 10% with 30% alcohol.....	1.63	100 ml	
	(3.48)		Betadine Skin Prep
Skin preparation, povidone iodine 10% with 70% alcohol.....	1.63	100 ml	
	(7.78)		Pfizer

Parasiticial Preparations

DIMETHICONE

* Lotn 4%	4.25	200 ml OP	✓ healthE Dimethicone 4% Lotion
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healthE Dimethicone 4% Lotion to be Principal Supply on 1 December 2022

IVERMECTIN – Special Authority see [SA1225 on the next page](#) – Retail pharmacy

Tab 3 mg – Up to 100 tab available on a PSO	17.20	4	✓ Stromectol
1) PSO for institutional use only. Must be endorsed with the name of the institution for which the PSO is required and a valid Special Authority for patient of that institution.			
2) Ivermectin available on BSO provided the BSO includes a valid Special Authority for a patient of the institution.			
3) For the purposes of subsidy of ivermectin, institution means age related residential care facilities, disability care facilities or prisons.			

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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►SA1225 **Special Authority for Subsidy**

Initial application — (Scabies) from any relevant practitioner. Approvals valid for 1 month for applications meeting the following criteria:

Both:

- 1 Applying clinician has discussed the diagnosis of scabies with a dermatologist, infectious disease physician or clinical microbiologist; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 The patient is in the community; and
 - 2.1.2 Any of the following:
 - 2.1.2.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
 - 2.1.2.2 The community patient is physically or mentally unable to comply with the application instructions of topical therapy; or
 - 2.1.2.3 The patient has previously tried and failed to clear infestation using topical therapy; or
 - 2.2 All of the following:
 - 2.2.1 The Patient is a resident in an institution; and
 - 2.2.2 All residents of the institution with scabies or at risk of carriage are to be treated for scabies concurrently; and
 - 2.2.3 Any of the following:
 - 2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
 - 2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or
 - 2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

Note: Ivermectin is no more effective than topical therapy for treatment of standard scabies infestation.

Initial application — (Other parasitic infections) only from an infectious disease specialist, clinical microbiologist or dermatologist. Approvals valid for 1 month for applications meeting the following criteria:

Any of the following:

- 1 Filaricides; or
- 2 Cutaneous larva migrans (creeping eruption); or
- 3 Strongyloidiasis.

Renewal — (Scabies) from any relevant practitioner. Approvals valid for 1 month for applications meeting the following criteria:

Both:

- 1 Applying clinician has discussed the diagnosis of scabies with a dermatologist, infectious disease physician or clinical microbiologist; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 The patient is in the community; and
 - 2.1.2 Any of the following:
 - 2.1.2.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
 - 2.1.2.2 The community patient is physically or mentally unable to comply with the application instructions of topical therapy; or
 - 2.1.2.3 The patient has previously tried and failed to clear infestation using topical therapy; or
 - 2.2 All of the following:
 - 2.2.1 The Patient is a resident in an institution; and
 - 2.2.2 All residents of the institution with scabies or at risk of carriage are to be treated for scabies concurrently; and
 - 2.2.3 Any of the following:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

continued...

- 2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- 2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or
- 2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

Note: Ivermectin is no more effective than topical therapy for treatment of standard scabies infestation.

Renewal — (Other parasitic infections) only from an infectious disease specialist, clinical microbiologist or dermatologist.

Approvals valid for 1 month for applications meeting the following criteria:

Any of the following:

- 1 Filaricides; or
- 2 Cutaneous larva migrans (creeping eruption); or
- 3 Strongyloidiasis.

PERMETHRIN

Crm 5%.....	5.75	30 g OP	✓ Lyderm
Lotn 5%	3.99	30 ml OP	✓ A-Scabies

Psoriasis and Eczema Preparations

ACITRETIN – Special Authority see [SA2024 below](#) – Retail pharmacy

Cap 10 mg	17.86	60	✓ Novatretin
Cap 25 mg	41.36	60	✓ Novatretin

» **SA2024** **Special Authority for Subsidy**

Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- 2 Applicant has an up to date knowledge of the safety issues around acitretin and is competent to prescribe acitretin; and
- 3 Either:
 - 3.1 Patient is of child bearing potential and the possibility of pregnancy has been excluded prior to commencement of treatment and patient has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and that they must not become pregnant during treatment and for a period of three years after the completion of treatment; or
 - 3.2 Patient is not of child bearing potential.

Renewal from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Either:

- 1 Patient is of child bearing potential and the possibility of pregnancy has been excluded prior to commencement of treatment and patient has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and that they must not become pregnant during treatment and for a period of three years after the completion of treatment; or
- 2 Patient is not of child bearing potential.

BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL

Foam spray 500 mcg with calcipotriol 50 mcg per g	59.95	60 g OP	✓ Enstilar
Gel 500 mcg with calcipotriol 50 mcg per g	39.35	60 g OP	✓ Daivobet
Oint 500 mcg with calcipotriol 50 mcg per g	15.90	30 g OP	✓ Daivobet

CALCIPOTRIOL

Oint 50 mcg per g	40.00	120 g OP	✓ Daivonex
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
COAL TAR				
Soln BP – Only in combination	36.25	200 ml	✓	Midwest
1) Up to 10% only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain				
2) With or without other dermatological galenicals.				
COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR				
Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and allantoin crm 2.5%	6.59 (8.00) 3.43 (4.35)	75 g OP 30 g OP		Egopsoryl TA Egopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR				
Soln 12% with salicylic acid 2% and sulphur 4% oint.....	4.97 7.95	25 g OP 40 g OP	✓ ✓	Coco-Scalp Coco-Scalp
PIMECROLIMUS – Special Authority see SA1970 below – Retail pharmacy				
a) Maximum of 15 g per prescription				
b) Note: a maximum of 15 g per prescription and no more than one prescription per 12 weeks.				
Cream 1%	28.50	15 g OP	✓	Elidel
►SA1970 Special Authority for Subsidy				
Initial application only from a dermatologist, paediatrician, ophthalmologist or any relevant practitioner on the recommendation of a dermatologist, paediatrician or ophthalmologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:				
Both:				
1 Patient has atopic dermatitis on the eyelid; and				
2 Patient has at least one of the following contraindications to topical corticosteroids: periorificial dermatitis, rosacea, documented epidermal atrophy, documented allergy to topical corticosteroids, cataracts, glaucoma, or raised intraocular pressure.				
PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORESCEIN – Only on a prescription				
* Soln 2.3% with trolamine laurilsulfate and fluorescein sodium	4.44	500 ml	✓	Pinetarsol
SALICYLIC ACID				
Powder – Only in combination	18.88	250 g	✓	Midwest
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain or collodion flexible				
2) With or without other dermatological galenicals.				
SULPHUR				
Precipitated – Only in combination	6.35	100 g	✓	Midwest
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain				
2) With or without other dermatological galenicals.				
TACROLIMUS				
Oint 0.1% – Special Authority see SA2074 on the next page – Retail pharmacy	33.00	30 g OP	✓	Zematop
a) Maximum of 30 g per prescription				
b) Note: a maximum of 30 g per prescription and no more than one prescription per 12 weeks.				

►SA2074 Special Authority for Subsidy

Initial application only from a dermatologist, paediatrician or any relevant practitioner on the recommendation of a dermatologist, paediatrician, . Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Patient has atopic dermatitis on the face; and
- 2 Patient has at least one of the following contraindications to topical corticosteroids: periorificial dermatitis, rosacea, documented epidermal atrophy or documented allergy to topical corticosteroids.

Scalp Preparations

BETAMETHASONE VALERATE			
* Scalp app 0.1%	9.84	100 ml OP	✓ <u>Beta Scalp</u>
CLOBETASOL PROPIONATE			
* Scalp app 0.05%	6.26	30 ml OP	✓ <u>Dermol</u>
HYDROCORTISONE BUTYRATE			
Scalp lotn 0.1%	6.57	100 ml OP	✓ <u>Locoid</u>
KETOCONAZOLE			
Shampoo 2%	3.23	100 ml OP	✓ <u>Sebizole</u> ✓ <u>Sebizole</u>
a) Maximum of 100 ml per prescription			
b) Only on a prescription			

Sunscreens

SUNSCREENS, PROPRIETARY – Subsidy by endorsement

Only if prescribed for a patient with severe photosensitivity secondary to a defined clinical condition and the prescription is endorsed accordingly.

Lotn,	5.10	200 g OP	✓ <u>Marine Blue Lotion</u> <u>SPF 50+</u>
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Wart Preparations

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, [page 68](#)

IMIQUIMOD			
Crm 5%, 250 mg sachet	21.72	24	✓ <u>Perrigo</u>
PODOPHYLLOTOXIN			
Soln 0.5%	33.60	3.5 ml OP	✓ <u>Condyline</u>
a) Maximum of 3.5 ml per prescription			
b) Only on a prescription			

Other Skin Preparations

Antineoplastics

FLUOROURACIL SODIUM			
Crm 5%	6.95	20 g OP	✓ <u>Efudix</u>

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Contraceptives - Non-hormonal				
Condoms				
CONDOMS				
* 49 mm – Up to 144 dev available on a PSO	11.42	144	✓	<u>Moments</u>
* 53 mm.....	0.95	10	✓	<u>Moments</u>
	11.64	144	✓	<u>Moments</u>
a) Maximum of 60 dev per prescription				
b) Up to 60 dev available on a PSO				
* 53 mm, 0.05 mm thickness.....	0.95	10	✓	<u>Moments</u>
	11.42	144	✓	<u>Moments</u>
a) Up to 60 dev available on a PSO				
b) Maximum of 60 dev per prescription				
* 53 mm, chocolate, brown	0.95	10	✓	<u>Moments</u>
	11.64	144	✓	<u>Moments</u>
a) Up to 60 dev available on a PSO				
b) Maximum of 60 dev per prescription				
* 53 mm, strawberry, red.....	0.95	10	✓	<u>Moments</u>
	11.64	144	✓	<u>Moments</u>
a) Up to 60 dev available on a PSO				
b) Maximum of 60 dev per prescription				
* 56 mm.....	0.97	10	✓	<u>Moments</u>
	11.64	144	✓	<u>Moments</u>
a) Maximum of 60 dev per prescription				
b) Up to 60 dev available on a PSO				
* 56 mm, 0.05 mm thickness.....	1.30	12	✓	<u>Gold Knight</u>
	15.57	144	✓	<u>Gold Knight</u>
a) Up to 60 dev available on a PSO				
b) Maximum of 60 dev per prescription				
* 56 mm, 0.05mm thickness (bulk pack)	14.61	144	✓	<u>Gold Knight</u>
a) Maximum of 60 dev per prescription				
b) Up to 60 dev available on a PSO				
* 56 mm, 0.08 mm thickness.....	0.97	10	✓	<u>Moments</u>
	11.64	144	✓	<u>Moments</u>
a) Up to 60 dev available on a PSO				
b) Maximum of 60 dev per prescription				
* 56 mm, 0.08 mm thickness, red	0.97	10	✓	<u>Moments</u>
	11.64	144	✓	<u>Moments</u>
a) Up to 60 dev available on a PSO				
b) Maximum of 60 dev per prescription				
* 56 mm, chocolate	1.30	12	✓	<u>Gold Knight</u>
	15.57	144	✓	<u>Gold Knight</u>
a) Up to 60 dev available on a PSO				
b) Maximum of 60 dev per prescription				
* 56 mm, strawberry.....	1.30	12	✓	<u>Gold Knight</u>
	15.57	144	✓	<u>Gold Knight</u>
a) Up to 60 dev available on a PSO				
b) Maximum of 60 dev per prescription				
* 60 mm.....	1.42	12	✓	<u>Gold Knight XL</u>
	14.87	144	✓	<u>Shield XL</u>
	17.02		✓	<u>Gold Knight XL</u>

- a) Maximum of 60 dev per prescription
 b) Up to 60 dev available on a PSO

\$29 Unapproved medicine supplied under Section 29

Sole Subsidised Supply

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
* 60 mm (bulk pack)	14.87	144	✓	Gold Knight XL
a) Maximum of 60 dev per prescription				
b) Up to 60 dev available on a PSO				

Contraceptive Devices

INTRA-UTERINE DEVICE

a) Up to 40 dev available on a PSO				
b) Only on a PSO				
* IUD 29.1 mm length x 23.2 mm width	18.45	1	✓	7 MED NSHA Silver/ Copper Short
			✓	Choice 380 7med Nsha Silver/ copper Short
			✓	Choice TT380 Short
* IUD 33.6 mm length x 29.9 mm width	18.45	1	✓	Choice TT380 Standard
* IUD 35.5 mm length x 19.6 mm width	15.50	1	✓	Choice Load 375

Contraceptives - Hormonal

Combined Oral Contraceptives

►SA0500 Special Authority for Alternate Subsidy

Initial application from any medical practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 Patient is on a Social Welfare benefit; or
 - 1.2 Patient has an income no greater than the benefit; and
- 2 Has tried at least one of the fully funded options and has been unable to tolerate it.

Renewal from any medical practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Patient is on a Social Welfare benefit; or
- 2 Patient has an income no greater than the benefit.

Notes: The approval numbers of Special Authorities approved after 1 November 1999 are interchangeable between Mercilon and Marvelon.

The additional subsidy will fund Mercilon and Marvelon up to the manufacturer's price for each of these products as identified on the Schedule at 1 November 1999.

Special Authorities approved before 1 November 1999 remain valid until the expiry date and can be renewed providing that women are still either:

- on a Social Welfare benefit; or
- have an income no greater than the benefit.

The approval numbers of Special Authorities approved before 1 November 1999 are interchangeable for products within the combined oral contraceptives and progestogen-only contraceptives groups, except Loette and Microgynon 20 ED

ETHINYLOESTRADIOL WITH DESOGESTREL

* Tab 20 mcg with desogestrel 150 mcg and 7 inert tab – Up to 84 tab available on a PSO.....	10.00	84	✓	Mercilon 28
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GENITO-URINARY SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ETHINYLOESTRADIOL WITH LEVONORGESTREL				
* Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets – Up to 112 tab available on a PSO	2.18 6.45	84 112	✓ ✓	Microgynon 20 ED Femme-Tab ED
* Tab 30 mcg with levonorgestrel 150 mcg..... (16.50)	6.62	63		Microgynon 30
a) Higher subsidy of \$15.00 per 63 tab with Special Authority see SA0500 on the previous page b) Up to 63 tab available on a PSO				
* Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets – Up to 112 tab available on a PSO	1.77 6.45	84 112	✓ ✓	Levlen ED Femme-Tab ED
ETHINYLOESTRADIOL WITH NORETHISTERONE				
Tab 35 mcg with norethisterone 1 mg and 7 inert tab – Up to 84 tab available on a PSO.....	6.95	84	✓	Brevinor 1/28
Tab 35 mcg with norethisterone 500 mcg and 7 inert tab – Up to 84 tab available on a PSO.....	21.99 29.32	84 112	✓ ✓	Norimin Norimin

Progestogen-only Contraceptives

► **SA0500** Special Authority for Alternate Subsidy

Initial application from any medical practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 Patient is on a Social Welfare benefit; or
 - 1.2 Patient has an income no greater than the benefit; and
- 2 Has tried at least one of the fully funded options and has been unable to tolerate it.

Renewal from any medical practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Patient is on a Social Welfare benefit; or
- 2 Patient has an income no greater than the benefit.

Notes: The approval numbers of Special Authorities approved after 1 November 1999 are interchangeable between Mercilon and Marvelon.

The additional subsidy will fund Mercilon and Marvelon up to the manufacturer's price for each of these products as identified on the Schedule at 1 November 1999.

Special Authorities approved before 1 November 1999 remain valid until the expiry date and can be renewed providing that women are still either:

- on a Social Welfare benefit; or
- have an income no greater than the benefit.

The approval numbers of Special Authorities approved before 1 November 1999 are interchangeable for products within the combined oral contraceptives and progestogen-only contraceptives groups, except Loette and Microgynon 20 ED

LEVONORGESTREL

* Tab 30 mcg – Up to 84 tab available on a PSO	16.50	84	✓	Microlut
	22.00	112	✓	Microlut
* Subdermal implant (2 × 75 mg rods) – Up to 3 pack available on a PSO.....	106.92	1	✓	Jadelle

MEDROXYPROGESTERONE ACETATE

Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO	7.98	1	✓	Depo-Provera
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
NORETHISTERONE				
Tab 350 mcg – Up to 84 tab available on a PSO	12.25	84	✓	Noriday 28

Emergency Contraceptives

LEVONORGESTREL				
* Tab 1.5 mg	4.95	1	✓	Postinor-1
a) Maximum of 2 tab per prescription				
b) Up to 5 tab available on a PSO				
c) Note: Direct Provision by a pharmacist permitted under the provisions in Part I of Section A.				

Antiandrogen Oral Contraceptives

Prescribers may code prescriptions "contraceptive" (code "O") when used as indicated for contraception. The period of supply and prescription charge will be as per other contraceptives, as follows:

- \$5.00 prescription charge (patient co-payment) will apply.
- prescription may be written for up to six months supply.

Prescriptions coded in any other way are subject to the non contraceptive prescription charges, and the non-contraceptive period of supply. ie. Prescriptions may be written for up to three months supply.

CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL

* Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs – Up to 168 tab available on a PSO	4.98	168	✓	Ginet
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Gynaecological Anti-infectives

ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID

Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate 0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator....	8.43 (24.15)	100 g OP		Aci-Jel
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CLOTRIMAZOLE

* Vaginal crm 1% with applicators.....	2.50	35 g OP	✓	Clomazol
* Vaginal crm 2% with applicators.....	3.00	20 g OP	✓	Clomazol

MICONAZOLE NITRATE

* Vaginal crm 2% with applicator	6.89	40 g OP	✓	Micreme
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NYSTATIN

Vaginal crm 100,000 u per 5 g with applicator(s)	4.00	75 g OP	✓	Nilstat
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Myometrial and Vaginal Hormone Preparations

ERGOMETRINE MALEATE

Inj 500 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	160.00	5	✓	DBL Ergometrine
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OESTRIOL

* Crm 1 mg per g with applicator.....	6.62	15 g OP	✓	Ovestin
* Pessaries 500 mcg	6.86	15	✓	Ovestin

OXYTOCIN – Up to 5 inj available on a PSO

Inj 5 iu per ml, 1 ml ampoule	3.98	5	✓	Oxytocin BNM
Inj 10 iu per ml, 1 ml ampoule	4.98	5	✓	Oxytocin BNM

OXYTOCIN WITH ERGOMETRINE MALEATE – Up to 5 inj available on a PSO

Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampoule	32.40	5	✓	Syntometrine
Syntometrine to be Principal Supply on 1 December 2022				

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Pregnancy Tests - hCG Urine

PREGNANCY TESTS - HCG URINE

- Up to 200 test available on a PSO
- Only on a PSO

Cassette	12.00	40 test OP	✓ Smith BioMed Rapid Pregnancy Test
	16.00		✓ David One Step Cassette Pregnancy Test

Urinary Agents

For urinary tract Infections refer to INFECTIONS, Antibacterials, [page 106](#)

5-Alpha Reductase Inhibitors

FINASTERIDE – Special Authority see [SA0928 below](#) – Retail pharmacy

* Tab 5 mg	4.81	100	✓ Ricit
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► [SA0928](#) **Special Authority for Subsidy**

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- Patient has symptomatic benign prostatic hyperplasia; and
- Either:
 - The patient is intolerant of non-selective alpha blockers or these are contraindicated; or
 - Symptoms are not adequately controlled with non-selective alpha blockers.

Note: Patients with enlarged prostates are the appropriate candidates for therapy with finasteride.

Alpha-1A Adrenoreceptor Blockers

TAMSULOSIN HYDROCHLORIDE – Special Authority see [SA1032 below](#) – Retail pharmacy

* Cap 400 mcg	22.31	100	✓ Tamsulosin-Rex
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► [SA1032](#) **Special Authority for Subsidy**

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- Patient has symptomatic benign prostatic hyperplasia; and
- The patient is intolerant of non-selective alpha blockers or these are contraindicated.

Other Urinary Agents

OXYBUTYNIN

* Tab 5 mg	5.42	100	✓ Alchemy Oxybutynin <small>S29</small>
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POTASSIUM CITRATE

Oral liq 3 mmol per ml – Special Authority see [SA1083 on the](#)

next page – Retail pharmacy	31.80	200 ml OP	✓ Biomed
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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►SA1083 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:

- 1 The patient has recurrent calcium oxalate urolithiasis; and
- 2 The patient has had more than two renal calculi in the two years prior to the application.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefitting from the treatment.

SODIUM CITRO-TARTRATE

* Grans eff 4 g sachets2.22 28 ✓ Ural

SOLIFENACIN SUCCINATE

Tab 5 mg2.05 30 ✓ Solifenacin Mylan
Tab 10 mg3.72 30 ✓ Solifenacin Mylan

Detection of Substances in Urine

ORTHO-TOLIDINE

* Compound diagnostic sticks7.50 50 test OP
(8.25) Hemastix

TETRABROMOPHENOL

* Blue diagnostic strips13.92 100 test OP ✓ Albustix

Obstetric Preparations

Antiprogesterones

MIFEPRISTONE

Tab 200 mg60.00 1 ✓ Mifegyne
180.00 3 ✓ Mifegyne

- a) Up to 15 tab available on a PSO
- b) Only on a PSO

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Calcium Homeostasis				
CALCITONIN				
* Inj 100 iu per ml, 1 ml ampoule	121.00	5	✓	Miacalcic
CINACALCET – Special Authority see SA1618 below – Retail pharmacy				
Tab 30 mg – Wastage claimable	42.06	28	✓	Cinacalcet Devatis
Tab 60 mg – Wastage claimable	84.12	28	✓	Cinacalcet Devatis

➡ **SA1618** Special Authority for Subsidy

Initial application only from a nephrologist or endocrinologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 The patient has been diagnosed with a parathyroid carcinoma (see Note); and
 - 1.2 The patient has persistent hypercalcaemia (serum calcium greater than or equal to 3 mmol/L) despite previous first-line treatments including sodium thiosulfate (where appropriate) and bisphosphonates; and
 - 1.3 The patient is symptomatic; or
- 2 All of the following:
 - 2.1 The patient has been diagnosed with calciphylaxis (calcific uraemic arteriopathy); and
 - 2.2 The patient has symptomatic (e.g. painful skin ulcers) hypercalcaemia (serum calcium greater than or equal to 3 mmol/L); and
 - 2.3 The patient's condition has not responded to previous first-line treatments including bisphosphonates and sodium thiosulfate.

Renewal only from a nephrologist or endocrinologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 The patient's serum calcium level has fallen to $< 3\text{mmol/L}$; and
- 2 The patient has experienced clinically significant symptom improvement.

Note: This does not include parathyroid adenomas unless these have become malignant.

ZOLEDRONIC ACID

Inj 4 mg per 5 ml, vial – Special Authority see [SA2109](#) below –

Retail pharmacy.....	18.00	1	✓ Zoledronic acid Mylan
			✓ Zoledronic acid Viatrix

➡ **SA2109** Special Authority for Subsidy

Initial application — (bone metastases) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Patient has hypercalcaemia of malignancy; or
- 2 Both:
 - 2.1 Patient has bone metastases or involvement; and
 - 2.2 Patient has severe bone pain resistant to standard first-line treatments; or
- 3 Both:
 - 3.1 Patient has bone metastases or involvement; and
 - 3.2 Patient is at risk of skeletal-related events pathological fracture, spinal cord compression, radiation to bone or surgery to bone.

Initial application — (early breast cancer*) from any relevant practitioner. Approvals valid for 3 years for applications meeting

continued...

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
continued...				
the following criteria:				
All of the following:				
1 Treatment to be used as adjuvant therapy for early breast cancer; and				
2 Patient has been amenorrhoeic for 12 months or greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and				
3 Treatment to be administered at a minimum interval of 6-monthly for a maximum of 3 years.				
Note: Indications marked with * are unapproved indications.				
Initial application — (symptomatic hypercalcaemia*) from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has symptomatic hypercalcaemia .				
Note: Indications marked with * are unapproved indications.				
Corticosteroids and Related Agents for Systemic Use				
BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETATE				
* Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	19.20	5		Celestone
	(36.96)			Chronodose
DEXAMETHASONE				
* Tab 0.5 mg – Up to 60 tab available on a PSO	1.50	30	✓	<u>Dexamethsone</u>
* Tab 4 mg – Up to 30 tab available on a PSO	2.65	30	✓	<u>Dexamethsone</u>
Oral liq 1 mg per ml	48.15	25 ml OP	✓	<u>Biomed</u>
DEXAMETHASONE PHOSPHATE				
Dexamethasone phosphate injection will not be funded for oral use.				
* Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	7.86	10	✓	Hameln
	9.25		✓	Dexamethasone Phosphate Panpharma
* Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	13.10	10	✓	Hameln
	16.37		✓	Dexamethasone Phosphate Panpharma
<i>(Dexamethasone Phosphate Panpharma Inj 4 mg per ml, 1 ml ampoule to be delisted 1 February 2023)</i>				
<i>(Dexamethasone Phosphate Panpharma Inj 4 mg per ml, 2 ml ampoule to be delisted 1 February 2023)</i>				
FLUDROCORTISONE ACETATE				
* Tab 100 mcg.....	11.46	100	✓	Florinef
Florinef to be Principal Supply on 1 December 2022				
HYDROCORTISONE				
* Tab 5 mg	8.10	100	✓	Douglas
* Tab 20 mg	20.32	100	✓	Douglas
* Inj 100 mg vial	4.38	1	✓	<u>Solu-Cortef</u>
a) Up to 5 inj available on a PSO				
b) Only on a PSO				
METHYLPREDNISOLONE				
* Tab 4 mg	112.00	100	✓	Medrol
* Tab 100 mg	223.10	20	✓	Medrol

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
METHYLPREDNISOLONE (AS SODIUM SUCCINATE)				
Inj 40 mg vial	22.30	1	✓	Solu-Medrol-Act-O-Vial
Inj 125 mg vial	34.10	1	✓	Solu-Medrol-Act-O-Vial
Inj 500 mg vial	26.88	1	✓	Solu-Medrol-Act-O-Vial
Inj 1 g vial	32.84	1	✓	Solu-Medrol
METHYLPREDNISOLONE ACETATE				
Inj 40 mg per ml, 1 ml vial	47.06	5	✓	Depo-Medrol
PREDNISOLONE				
* Oral liq 5 mg per ml – Up to 30 ml available on a PSO	6.00	30 ml OP	✓	Redipred
Restricted to children under 12 years of age.				
PREDNISONE				
* Tab 1 mg	18.58	500	✓	Apo-Prednisone
			✓	Prednisone Clinect
* Tab 2.5 mg	21.04	500	✓	Apo-Prednisone
			✓	Prednisone Clinect
* Tab 5 mg – Up to 30 tab available on a PSO	19.30	500	✓	Apo-Prednisone
			✓	Prednisone Clinect
* Tab 20 mg – Up to 30 tab available on a PSO	50.51	500	✓	Apo-Prednisone
			✓	Prednisone Clinect
<i>(Apo-Prednisone Tab 1 mg to be delisted 1 November 2022)</i>				
<i>(Apo-Prednisone Tab 2.5 mg to be delisted 1 November 2022)</i>				
<i>(Apo-Prednisone Tab 5 mg to be delisted 1 November 2022)</i>				
<i>(Apo-Prednisone Tab 20 mg to be delisted 1 November 2022)</i>				
TETRACOSACTRIN				
* Inj 250 mcg per ml, 1 ml ampoule	75.00	1	✓	AU Synacthen
			✓	Synacthen
			✓	UK Synacthen
* Inj 1 mg per ml, 1 ml ampoule	690.00	1	✓	Synacthen Depot
			✓	Synacthene
				Retard <small>\$29</small>
<i>(AU Synacthen Inj 250 mcg per ml, 1 ml ampoule to be delisted 1 March 2023)</i>				
TRIAMCINOLONE ACETONIDE				
Inj 10 mg per ml, 1 ml ampoule	20.80	5	✓	Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule	51.10	5	✓	Kenacort-A 40

Sex Hormones Non Contraceptive

Androgen Agonists and Antagonists

CYPROTERONE ACETATE				
Tab 50 mg	14.37	50	✓	Siterone
Tab 100 mg	28.03	50	✓	Siterone
TESTOSTERONE				
Patch 5 mg per day	90.00	30	✓	Androderm

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
TESTOSTERONE CIPIONATE				
Inj 100 mg per ml, 10 ml vial.....	85.00	1	✓	Depo-Testosterone
TESTOSTERONE ESTERS				
Inj 250 mg per ml, 1 ml.....	12.98	1	✓	Sustanon Ampoules
TESTOSTERONE UNDECANOATE				
Cap 40 mg – Subsidy by endorsement	21.00	60	✓	Andriol Testocaps
	35.00	100	✓	Steril-Gene ^{S29}
Subsidy by endorsement – subsidised for patients who were taking testosterone undecanoate cap 40mg prior to 1 November 2021 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of testosterone undecanoate cap 40 mg in the preceding 12 months.				
Inj 250 mg per ml, 4 ml vial.....	86.00	1	✓	Reandron 1000

Hormone Replacement Therapy - Systemic

Prescribing Guideline

HRT should be taken at the lowest dose for the shortest period of time necessary to control symptoms. Patients should be reviewed 6 monthly in line with the updated NZGG “Evidence-based Best Practice Guideline on Hormone Replacement Therapy March 2004”.

Oestrogens

OESTRADIOL – See prescribing guideline [above](#)

* Tab 1 mg	4.12	28 OP		
	(11.10)			Estrofem
* Tab 2 mg	4.12	28 OP		
	(11.10)			Estrofem
Patch 50 mcg per 24 hours	7.04	4	✓	Climara
a) No more than 1 patch per week				
b) Only on a prescription				
Patch 25 mcg per day.....	6.12	8	✓	Estradot
a) No more than 2 patch per week				
b) Only on a prescription				
Patch 50 mcg per day.....	7.04	8	✓	Estradot 50 mcg
	9.22		✓	Estradiol TDP
				Mylan ^{S29}
a) No more than 2 patch per week				
b) Only on a prescription				
Patch 75 mcg per day.....	7.91	8	✓	Estradot
	10.60		✓	Estradiol TDP
				Mylan ^{S29}
a) No more than 2 patch per week				
b) Only on a prescription				
Patch 100 mcg per day.....	7.91	8	✓	Estradot
a) No more than 2 patch per week				
b) Only on a prescription				
OESTRADIOL VALERATE – See prescribing guideline above				
* Tab 1 mg	12.36	84	✓	Progynova
* Tab 2 mg	12.36	84	✓	Progynova

▲Three months supply may be dispensed at one time if endorsed “certified exemption” by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
OESTROGENS – See prescribing guideline on the previous page				
* Conjugated, equine tab 300 mcg.....	3.01 (17.50)	28		Premarin
* Conjugated, equine tab 625 mcg.....	4.12 (17.50)	28		Premarin

Progestogens

MEDROXYPROGESTERONE ACETATE – See prescribing guideline [on the previous page](#)

* Tab 2.5 mg	4.69	30	✓ Provera
	8.75	56	✓ Provera S29 S29
* Tab 5 mg	9.80	56	✓ Provera S29 S29
	17.50	100	✓ Provera
* Tab 10 mg	8.94	30	✓ Provera

Progestogen and Oestrogen Combined Preparations

OESTRADIOL WITH NORETHISTERONE – See prescribing guideline [on the previous page](#)

* Tab 1 mg with 0.5 mg norethisterone acetate	5.40 (18.10)	28 OP		Kliovance
* Tab 2 mg with 1 mg norethisterone acetate	5.40 (18.10)	28 OP		Kliogest
* Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg oestradiol tab (12) and 1 mg oestradiol tab (6).....	5.40 (18.10)	28 OP		Trisequens

Other Oestrogen Preparations

ETHINYLOESTRADIOL – Subsidy by endorsement

Subsidy by endorsement – Subsidised for patients who were taking ethinyloestradiol prior to 1 March 2022 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of ethinyloestradiol.

Tab 10 mcg.....	17.60	100	✓ NZ Medical and Scientific
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(NZ Medical and Scientific Tab 10 mcg to be delisted 1 February 2023)

OESTRIOL

* Tab 2 mg	7.00	30	✓ Ovestin
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Other Progestogen Preparations

LEVONORGESTREL

* Intra-uterine device 52 mg.....	269.50	1	✓ Mirena
* Intra-uterine device 13.5 mg.....	215.60	1	✓ Jaydess

MEDROXYPROGESTERONE ACETATE

Tab 100 mg	116.15	100	✓ Provera HD
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NORETHISTERONE

* Tab 5 mg – Up to 30 tab available on a PSO	5.49	30	✓ Primolut N
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PROGESTERONE

Cap 100 mg – Special Authority see [SA1609 on the next page](#)

– Retail pharmacy.....	16.50	30	✓ Utrogestan
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1609 Special Authority for Subsidy

Initial application only from an obstetrician or gynaecologist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 For the prevention of pre-term labour*; and
- 2 Either:
 - 2.1 The patient has a short cervix on ultrasound (defined as < 25 mm at 16 to 28 weeks); or
 - 2.2 The patient has a history of pre-term birth at less than 28 weeks.

Renewal only from an obstetrician or gynaecologist. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 For the prevention of pre-term labour*; and
- 2 Treatment is required for second or subsequent pregnancy; and
- 3 Either:
 - 3.1 The patient has a short cervix on ultrasound (defined as < 25 mm at 16 to 28 weeks); or
 - 3.2 The patient has a history of pre-term birth at less than 28 weeks.

Note: Indications marked with * are unapproved indications.

Thyroid and Antithyroid Agents

CARBIMAZOLE

* Tab 5 mg	7.56	100	✓ <u>Neo-Mercazole</u>
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LEVOTHYROXINE

* Tab 25 mcg.....	5.55	90	✓ <u>Synthroid</u>
* Tab 50 mcg.....	1.71	28	✓ <u>Mercury Pharma</u>
	5.79	90	✓ <u>Synthroid</u>
	64.28	1,000	✓ <u>Eltroxin</u>
* Tab 100 mcg.....	1.78	28	✓ <u>Mercury Pharma</u>
	6.01	90	✓ <u>Synthroid</u>
	66.78	1,000	✓ <u>Eltroxin</u>

PROPYLTHIOURACIL – Special Authority see [SA1199 below](#) – Retail pharmacy

Propylthiouracil is not recommended for patients under the age of 18 years unless the patient is pregnant and other treatments are contraindicated.

Tab 50 mg	35.00	100	✓ <u>PTU</u> <small>\$29</small>
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►SA1199 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 The patient has hyperthyroidism; and
- 2 The patient is intolerant of carbimazole or carbimazole is contraindicated.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefitting from the treatment.

Trophic Hormones

Growth Hormones

SOMATROPIN (OMNITROPE) – Special Authority see [SA2032 on the next page](#) – Retail pharmacy

* Inj 5 mg cartridge.....	69.75	1	✓ <u>Omnitrope</u>
* Inj 10 mg cartridge.....	69.75	1	✓ <u>Omnitrope</u>
* Inj 15 mg cartridge.....	139.50	1	✓ <u>Omnitrope</u>

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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►SA2032 Special Authority for Subsidy

Initial application — (growth hormone deficiency in children) only from a paediatric endocrinologist or endocrinologist.

Approvals valid for 9 months for applications meeting the following criteria:

Either:

- 1 Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of life, or from samples during established hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device); or
- 2 All of the following:
 - 2.1 Height velocity < 25th percentile for age adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985); and
 - 2.2 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
 - 2.3 Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children who are 5 years or older, GH testing with sex steroid priming is required; and
 - 2.4 If the patient has been treated for a malignancy, they should be disease free for at least one year based upon follow-up laboratory and radiological imaging appropriate for the malignancy, unless there are strong medical reasons why this is either not necessary or appropriate; and
 - 2.5 Appropriate imaging of the pituitary gland has been obtained.

Renewal — (growth hormone deficiency in children) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 A current bone age is 14 years or under (female patients) or 16 years or under (male patients); and
- 2 Height velocity is greater than or equal to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth hormone treatment, as calculated over six months using the standards of Tanner and Davis (1985); and
- 3 Height velocity is greater than or equal to 2.0 cm per year, as calculated over 6 months; and
- 4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone treatment has occurred; and
- 5 No malignancy has developed since starting growth hormone.

Initial application — (Turner syndrome) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient has a post-natal genotype confirming Turner Syndrome; and
- 2 Height velocity is < 25th percentile over 6-12 months using the standards of Tanner and Davies (1985); and
- 3 A current bone age is < 14 years.

Renewal — (Turner syndrome) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Height velocity is greater than or equal to 50th percentile for age (while on growth hormone calculated over 6 to 12 months using the Ranke's Turner Syndrome growth velocity charts); and
- 2 Height velocity is greater than or equal to 2 cm per year, calculated over six months; and
- 3 A current bone age is 14 years or under ; and
- 4 No serious adverse effect that the specialist considers is likely to be attributable to growth hormone treatment has occurred; and
- 5 No malignancy has developed since starting growth hormone.

Initial application — (short stature without growth hormone deficiency) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

- 1 The patient's height is more than 3 standard deviations below the mean for age or for bone age if there is marked growth acceleration or delay; and
- 2 Height velocity is < 25th percentile for age (adjusted for bone age/pubertal status if appropriate), as calculated over 6 to 12 months using the standards of Tanner and Davies(1985); and
- 3 A current bone age is < 14 years or under (female patients) or < 16 years (male patients); and
- 4 The patient does not have severe chronic disease (including malignancy or recognized severe skeletal dysplasia) and is not receiving medications known to impair height velocity.

Renewal — (short stature without growth hormone deficiency) only from a paediatric endocrinologist or endocrinologist.

Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985); and
- 2 Height velocity is greater than or equal to 2 cm per year as calculated over six months; and
- 3 A current bone age is 14 years or under (female patients) or 16 years or under (male patients); and
- 4 No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred.

Initial application — (short stature due to chronic renal insufficiency) only from a paediatric endocrinologist, endocrinologist or renal physician on the recommendation of a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient's height is more than 2 standard deviations below the mean; and
- 2 Height velocity is < 25th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985); and
- 3 A current bone age is to 14 years or under (female patients) or to 16 years or under (male patients); and
- 4 The patient is metabolically stable, has no evidence of metabolic bone disease and absence of any other severe chronic disease; and
- 5 The patient is under the supervision of a specialist with expertise in renal medicine; and
- 6 Either:
 - 6.1 The patient has a GFR less than or equal to 30 ml/min/1.73m² as measured by the Schwartz method (Height(cm)/plasma creatinine (umol/l) × 40 = corrected GFR (ml/min/1.73m² in a child who may or may not be receiving dialysis; or
 - 6.2 The patient has received a renal transplant and has received < 5mg/ m²/day of prednisone or equivalent for at least 6 months..

Renewal — (short stature due to chronic renal insufficiency) only from a paediatric endocrinologist, endocrinologist or renal physician on the recommendation of a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985); and
- 2 Height velocity is greater than or equal to 2 cm per year as calculated over six months; and
- 3 A current bone age is 14 years or under (female patients) or 16 years or under (male patients); and
- 4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone has occurred; and
- 5 No malignancy has developed after growth hormone therapy was commenced; and
- 6 The patient has not experienced significant biochemical or metabolic deterioration confirmed by diagnostic results; and
- 7 The patient has not received renal transplantation since starting growth hormone treatment; and
- 8 If the patient requires transplantation, growth hormone prescription should cease before transplantation and a new application should be made after transplantation based on the above criteria.

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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Initial application — (Prader-Willi syndrome) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria; and
- 2 The patient is aged six months or older; and
- 3 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
- 4 Sleep studies or overnight oximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon; and
- 5 Either:
 - 5.1 Both:
 - 5.1.1 The patient is aged two years or older; and
 - 5.1.2 There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months; or
 - 5.2 The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation.

Renewal — (Prader-Willi syndrome) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985); and
- 2 Height velocity is greater than or equal to 2 cm per year as calculated over six months; and
- 3 A current bone age is 14 years or under (female patients) or 16 years or under (male patients); and
- 4 No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred; and
- 5 No malignancy has developed after growth hormone therapy was commenced; and
- 6 The patient has not developed type II diabetes or uncontrolled obesity as defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months.

Initial application — (adults and adolescents) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient has a medical condition that is known to cause growth hormone deficiency (e.g. surgical removal of the pituitary for treatment of a pituitary tumour); and
- 2 The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses; and
- 3 The patient has severe growth hormone deficiency (see notes); and
- 4 The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex; and
- 5 The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®).

Notes: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of less than or equal to 3 mcg per litre during an adequately performed insulin tolerance test (ITT) or glucagon stimulation test.

Patients with one or more additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patients with isolated growth hormone deficiency require two growth hormone stimulation tests, of which, one should be ITT unless otherwise contraindicated. Where an additional test is required, an arginine provocation test can be used with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre.

The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until the serum IGF-I is within 1 standard deviation of the mean normal value for age and sex; and

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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

Dose of somatropin not to exceed 0.7 mg per day for male patients, or 1 mg per day for female patients.

At the commencement of treatment for hypopituitarism, patients must be monitored for any required adjustment in replacement doses of corticosteroid and levothyroxine.

Renewal — (adults and adolescents) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 All of the following:
 - 1.1 The patient has been treated with somatropin for < 12 months; and
 - 1.2 There has been an improvement in Quality of Life defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA®) score from baseline; and
 - 1.3 Serum IGF-I levels have been increased within ±1SD of the mean of the normal range for age and sex; and
 - 1.4 The dose of somatropin has not exceeded 0.7 mg per day for male patients, or 1 mg per day for female patients; or
- 2 All of the following:
 - 2.1 The patient has been treated with somatropin for more than 12 months; and
 - 2.2 The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDA® score on treatment (other than due to obvious external factors such as external stressors); and
 - 2.3 Serum IGF-I levels have continued to be maintained within ±1SD of the mean of the normal range for age and sex (other than for obvious external factors); and
 - 2.4 The dose of somatropin has not exceeded 0.7 mg per day for male patients or 1 mg per day for female patients; or
- 3 All of the following:
 - 3.1 The patient has had a Special Authority approval for somatropin for childhood deficiency in children and no longer meets the renewal criteria under this indication; and
 - 3.2 The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses; and
 - 3.3 The patient has severe growth hormone deficiency (see notes); and
 - 3.4 The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex; and
 - 3.5 The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®).

Notes: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of less than or equal to 3 mcg per litre during an adequately performed insulin tolerance test (ITT) or glucagon stimulation test.

Patients with one or more additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patients with isolated growth hormone deficiency require two growth hormone stimulation tests, of which, one should be ITT unless otherwise contraindicated. Where an additional test is required, an arginine provocation test can be used with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre.

The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until the serum IGF-I is within 1 standard deviation of the mean normal value for age and sex; and

Dose of somatropin not to exceed 0.7 mg per day for male patients, or 1 mg per day for female patients.

At the commencement of treatment for hypopituitarism, patients must be monitored for any required adjustment in replacement doses of corticosteroid and levothyroxine.

GnRH Analogues

GOSERELIN

Implant 3.6 mg, syringe	65.68	1	✓ Teva
Implant 10.8 mg, syringe	122.37	1	✓ Teva

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LEUPRORELIN				
Additional subsidy by endorsement where the patient is a child or adolescent and is unable to tolerate administration of goserelin and the prescription is endorsed accordingly.				
Inj 3.75 mg prefilled dual chamber syringe – Higher subsidy of				
\$221.60 per 1 inj with Endorsement.....	66.48	1		
	(221.60)			Lucrin Depot 1-month
Inj 11.25 mg prefilled dual chamber syringe – Higher subsidy of \$591.68 per 1 inj with Endorsement.....	177.50	1		
	(591.68)			Lucrin Depot 3-month

Vasopressin Agonists

DESMOPRESSIN				
Wafer 120 mcg	47.00	30	✓	Minirin Melt
DESMOPRESSIN ACETATE				
Tab 100 mcg.....	25.00	30	✓	Minirin
Tab 200 mcg.....	54.45	30	✓	Minirin
▲ Nasal spray 10 mcg per dose.....	27.95	6 ml OP	✓	Desmopressin- PH&T
Inj 4 mcg per ml, 1 ml	67.18	10	✓	Minirin

Other Endocrine Agents

CABERGOLINE				
Tab 0.5 mg – Maximum of 2 tab per prescription; can be waived by Special Authority see SA2070 below.....	3.75	2	✓	Dostinex
	15.20	8	✓	Dostinex

»SA2070 Special Authority for Waiver of Rule

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Hyperprolactinemia; or
- 2 Acromegaly*; or
- 3 Inhibition of lactation.

Renewal — (for patients who have previously been funded under Special Authority form SA1031) from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has previously held a valid Special Authority which has expired and the treatment remains appropriate and the patient is benefiting from treatment.

Note: Indication marked with * is an unapproved indication.

CLOMIFENE CITRATE				
Tab 50 mg	29.84	10	✓	Mylan Clomiphen <small>\$29</small>
METYPAPONE				
Cap 250 mg.....	558.00	50	✓	Metopirone

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Anthelmintics

ALBENDAZOLE – Special Authority see [SA1318 below](#) – Retail pharmacy

Tab 400 mg	469.20	60	✓ Eskazole ^{S29}
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►SA1318 Special Authority for Subsidy

Initial application only from an infectious disease specialist or clinical microbiologist. Approvals valid for 6 months where the patient has hydatids.

Renewal only from an infectious disease specialist or clinical microbiologist. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefitting from the treatment.

MEBENDAZOLE – Only on a prescription

Tab 100 mg	7.97	6	✓ Vermox
Oral liq 100 mg per 5 ml	2.18	15 ml	Vermox
	(7.53)		

PRAZIQUANTEL

Tab 600 mg	68.00	8	✓ Biltricide
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Antibacterials

- a) For topical antibacterials, refer to DERMATOLOGICALS, [page 61](#)
b) For anti-infective eye preparations, refer to SENSORY ORGANS, [page 239](#)

Cephalosporins and Cephamycins

CEFACLOR MONOHYDRATE

Cap 250 mg	24.70	100	✓ Ranbaxy-Cefaclor ✓ Ranbaxy-Cefaclor ^{S29} ^{S29}
Grans for oral liq 125 mg per 5 ml – Wastage claimable.....	3.53	100 ml	✓ Ranbaxy-Cefaclor ✓ Ranbaxy-Cefaclor ^{S29} ^{S29}

CEFALEXIN

Cap 250 mg	3.33	20	✓ Cephalexin ABM
Cap 500 mg	5.95	20	✓ Cephalexin ABM
Grans for oral liq 25 mg per ml – Wastage claimable.....	7.88	100 ml	✓ Flynn
	8.75		✓ Cefalexin Sandoz
Grans for oral liq 50 mg per ml – Wastage claimable.....	10.38	100 ml	✓ Flynn
	11.75		✓ Cefalexin Sandoz

(Cefalexin Sandoz Grans for oral liq 25 mg per ml to be delisted 1 January 2023)

(Cefalexin Sandoz Grans for oral liq 50 mg per ml to be delisted 1 January 2023)

CEFAZOLIN – Subsidy by endorsement

Only if prescribed for dialysis or cellulitis in accordance with a Health NZ Hospital approved protocol and the prescription is endorsed accordingly.

Inj 500 mg vial	3.39	5	✓ AFT
Inj 1 g vial	3.49	5	✓ AFT

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CEFTRIAXONE – Subsidy by endorsement				
a) Up to 10 inj available on a PSO				
b) Subsidised only if prescribed for a dialysis or cystic fibrosis patient, or the treatment of gonorrhoea, or the treatment of pelvic inflammatory disease, or the treatment of suspected meningococcal disease, and the prescription or PSO is endorsed accordingly.				
Inj 500 mg vial	0.89	1	✓	Ceftriaxone-AFT
Inj 1 g vial	3.99	5	✓	Ceftriaxone-AFT
CEFUROXIME AXETIL – Subsidy by endorsement				
Only if prescribed for prophylaxis of endocarditis and the prescription is endorsed accordingly.				
Tab 250 mg	45.93	50	✓	Zinnat

Macrolides

AZITHROMYCIN – Maximum of 5 days treatment per prescription; can be waived by Special Authority see [SA1683 below](#)

A maximum of 24 months of azithromycin treatment for non-cystic fibrosis bronchiectasis will be subsidised on Special Authority.

Tab 250 mg	8.19	30	✓	Apo-Azithromycin
Tab 500 mg – Up to 8 tab available on a PSO	2.57	2	✓	Zithromax
Grans for oral liq 200 mg per 5 ml (40 mg per ml) – Wastage claimable	16.97	15 ml	✓	Zithromax

► [SA1683](#) Special Authority for Waiver of Rule

Initial application — (bronchiolitis obliterans syndrome, cystic fibrosis and atypical Mycobacterium infections) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Patient has received a lung transplant, stem cell transplant, or bone marrow transplant and requires treatment for bronchiolitis obliterans syndrome*; or
- 2 Patient has received a lung transplant and requires prophylaxis for bronchiolitis obliterans syndrome*; or
- 3 Patient has cystic fibrosis and has chronic infection with *Pseudomonas aeruginosa* or *Pseudomonas*-related gram negative organisms*; or
- 4 Patient has an atypical *Mycobacterium* infection.

Note: Indications marked with * are unapproved indications.

Initial application — (non-cystic fibrosis bronchiectasis*) only from a respiratory specialist or paediatrician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 For prophylaxis of exacerbations of non-cystic fibrosis bronchiectasis*; and
- 2 Patient is aged 18 and under; and
- 3 Either:
 - 3.1 Patient has had 3 or more exacerbations of their bronchiectasis, within a 12 month period; or
 - 3.2 Patient has had 3 acute admissions to hospital for treatment of infective respiratory exacerbations within a 12 month period.

Note: Indications marked with * are unapproved indications.

Renewal — (non-cystic fibrosis bronchiectasis*) only from a respiratory specialist or paediatrician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has completed 12 months of azithromycin treatment for non-cystic fibrosis bronchiectasis; and
- 2 Following initial 12 months of treatment, the patient has not received any further azithromycin treatment for non-cystic fibrosis bronchiectasis for a further 12 months, unless considered clinically inappropriate to stop treatment; and
- 3 The patient will not receive more than a total of 24 months' azithromycin cumulative treatment (see note).

The patient must not have had more than 1 prior approval.

Note: No further renewals will be subsidised. A maximum of 24 months of azithromycin treatment for non-cystic fibrosis bronchiectasis will be subsidised. Indications marked with * are unapproved indications

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
CLARITHROMYCIN – Maximum of 500 mg per prescription; can be waived by Special Authority see SA1857 below			
Tab 250 mg	8.53	14	✓ Klacid
Grans for oral liq 250 mg per 5 ml – Wastage claimable.....	192.00	50 ml	✓ Klacid
► SA1857 Special Authority for Waiver of Rule			
Initial application — (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician.			
Approvals valid for 2 years for applications meeting the following criteria:			
Either:			
1 Atypical mycobacterial infection; or			
2 Mycobacterium tuberculosis infection where there is drug-resistance or intolerance to standard pharmaceutical agents.			
Initial application — (Helicobacter pylori eradication) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:			
Both:			
1 For the eradication of helicobacter pylori in a patient unable to swallow tablets; and			
2 For use only in combination with omeprazole and amoxicillin as part of a triple therapy regimen.			
Initial application — (Prophylaxis of infective endocarditis) from any relevant practitioner. Approvals valid for 3 months where prophylaxis of infective endocarditis associated with surgical or dental procedures if amoxicillin is contra-indicated.			
Renewal — (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician.			
Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.			
ERYTHROMYCIN (AS LACTOBIONATE)			
Inj 1 g vial	10.00	1	✓ Erythrocin IV
Erythrocin IV to be Principal Supply on 1 December 2022			
ERYTHROMYCIN ETHYL SUCCINATE			
Tab 400 mg	16.95	100	✓ E-Mycin
a) Up to 20 tab available on a PSO			
b) Up to 2 x the maximum PSO quantity for RFPP			
Grans for oral liq 200 mg per 5 ml	5.00	100 ml	✓ E-Mycin
a) Up to 300 ml available on a PSO			
b) Up to 2 x the maximum PSO quantity for RFPP			
c) Wastage claimable			
Grans for oral liq 400 mg per 5 ml	6.77	100 ml	✓ E-Mycin
a) Up to 200 ml available on a PSO			
b) Wastage claimable			
ROXITHROMYCIN			
Tab disp 50 mg.....	8.29	10	✓ Rulide D
Restricted to children under 12 years of age.			
Tab 150 mg	8.28	50	✓ Arrow-Roxithromycin
Tab 300 mg	16.33	50	✓ Arrow-Roxithromycin

(Rulide D Tab disp 50 mg to be delisted 1 March 2023)

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Penicillins				
AMOXICILLIN				
Cap 250 mg.....	22.50	500	✓	Alphamox
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP				
Cap 500 mg.....	36.98	500	✓	Alphamox
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP				
Grans for oral liq 125 mg per 5 ml.....	1.40	100 ml	✓	Alphamox 125
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml.....	1.73	100 ml	✓	Alphamox 250
a) Up to 300 ml available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP				
c) Wastage claimable				
Inj 250 mg vial	15.97	10	✓	Ibiamox
Inj 500 mg vial	17.43	10	✓	Ibiamox
Inj 1 g vial – Up to 5 inj available on a PSO	21.64	10	✓	Ibiamox
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg – Up to 30 tab available on a PSO	0.89	10	✓	Curam Duo 500/125
Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25 mg per ml.....	6.50	100 ml	✓	Augmentin
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq amoxicillin 50 mg with clavulanic acid 12.5 mg per ml – Up to 200 ml available on a PSO	2.20	100 ml OP	✓	Curam
BENZATHINE BENZYL PENICILLIN				
Inj 900 mg (1.2 million units) in 2.3 ml syringe – Up to 5 inj available on a PSO	375.97	10	✓	Bicillin LA
BENZYL PENICILLIN SODIUM [PENICILLIN G]				
Inj 600 mg (1 million units) vial – Up to 5 inj available on a PSO	11.09	10	✓	Sandoz
FLUCLOXACILLIN				
Cap 250 mg – Up to 30 cap available on a PSO.....	15.79	250	✓	Flucloxacillin-AFT
Cap 500 mg – Up to 30 cap available on a PSO.....	52.99	500	✓	Flucloxacillin-AFT
Grans for oral liq 25 mg per ml.....	3.29	100 ml	✓	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 50 mg per ml.....	3.68	100 ml	✓	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Inj 250 mg vial	17.56	10	✓	Flucloxin
Inj 500 mg vial	18.87	10	✓	Flucloxin
Inj 1 g vial – Up to 5 inj available on a PSO	5.70	5	✓	Flucil

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PHENOXYMETHYLPENICILLIN (PENICILLIN V)				
Cap 250 mg – Up to 30 cap available on a PSO.....	3.84	50	✓	Cilicaine VK
Cap 500 mg.....	6.86	50	✓	Cilicaine VK
a) Up to 20 cap available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP				
Grans for oral liq 125 mg per 5 ml.....	3.40	100 ml	✓	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml.....	4.24	100 ml	✓	AFT
a) Up to 300 ml available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP				
c) Wastage claimable				
PROCAINE PENICILLIN				
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO.....	123.50	5	✓	Cilicaine
<i>(Cilicaine Inj 1.5 g in 3.4 ml syringe to be delisted 1 February 2023)</i>				
Tetracyclines				
DOXYCYCLINE				
* Tab 100 mg – Up to 30 tab available on a PSO.....	64.43	500	✓	Doxine
MINOCYCLINE HYDROCHLORIDE				
* Tab 50 mg – Additional subsidy by Special Authority see				
SA1355 below – Retail pharmacy	5.79	60		Mino-tabs
	(12.05)			
* Cap 100 mg.....	19.32	100		Minomycin
	(52.04)			
SA1355 Special Authority for Manufacturers Price				
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has rosacea.				
TETRACYCLINE – Special Authority see SA1332 below – Retail pharmacy				
Tab 250 mg	21.42	28	✓	Accord S29
SA1332 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:				
Both:				
1 For the eradication of helicobacter pylori following unsuccessful treatment with appropriate first-line therapy; and				
2 For use only in combination with bismuth as part of a quadruple therapy regimen.				
Other Antibiotics				
For topical antibiotics, refer to DERMATOLOGICALS, page 61				
CIPROFLOXACIN				
Recommended for patients with any of the following:				
i) microbiologically confirmed and clinically significant pseudomonas infection; or				
ii) prostatitis; or				
iii) pyelonephritis; or				
iv) gonorrhoea.				
Tab 250 mg – Up to 5 tab available on a PSO.....	2.42	28	✓	Cipflox
Tab 500 mg – Up to 5 tab available on a PSO	3.40	28	✓	Cipflox
Tab 750 mg	5.95	28	✓	Cipflox

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

INFECTIONS - AGENTS FOR SYSTEMIC USE

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CLINDAMYCIN				
Cap hydrochloride 150 mg	4.61	24	✓	Dalacin C
Inj phosphate 150 mg per ml, 4 ml ampoule	39.00	10	✓	Dalacin C
COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist – Subsidy by endorsement				
Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.				
Inj 150 mg	65.00	1	✓	Colistin-Link
GENTAMICIN SULPHATE				
Inj 10 mg per ml, 1 ml ampoule – Subsidy by endorsement.....	95.00	5	✓	DBL Gentamicin
Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly.				
Inj 10 mg per ml, 2 ml ampoule – Subsidy by endorsement.....	91.00	5	✓	Wockhardt ^{\$29}
	182.00	10	✓	Teligent ^{\$29}
Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly.				
Inj 40 mg per ml, 2 ml ampoule – Subsidy by endorsement.....	17.50	10	✓	Pfizer
	87.50	50	✓	Pfizer
Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly.				
MOXIFLOXACIN – Special Authority see SA1740 below – Retail pharmacy				
No patient co-payment payable				
Tab 400 mg	42.00	5	✓	Avelox

➔SA1740 Special Authority for Subsidy

Initial application — (Tuberculosis) only from a respiratory specialist or infectious disease specialist. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

1 Both:

1.1 Active tuberculosis*; and

1.2 Any of the following:

1.2.1 Documented resistance to one or more first-line medications; or

1.2.2 Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents; or

1.2.3 Impaired visual acuity (considered to preclude ethambutol use); or

1.2.4 Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or

1.2.5 Significant documented intolerance and/or side effects following a reasonable trial of first-line medications; or

2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated.*; or

3 Patient is under five years of age and has had close contact with a confirmed multi-drug resistant tuberculosis case.

Note: Indications marked with * are unapproved indications.

Renewal only from a respiratory specialist or infectious disease specialist. Approvals valid for 1 year where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (Mycoplasma genitalium) only from a sexual health specialist or Practitioner on the recommendation of a sexual health specialist. Approvals valid for 1 month for applications meeting the following criteria:

All of the following:

1 Has nucleic acid amplification test (NAAT) confirmed Mycoplasma genitalium* and is symptomatic; and

2 Either:

2.1 Has tried and failed to clear infection using azithromycin; or

2.2 Has laboratory confirmed azithromycin resistance; and

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
continued...				
3 Treatment is only for 7 days.				
Initial application — (Penetrating eye injury) only from an ophthalmologist. Approvals valid for 1 month where the patient requires prophylaxis following a penetrating eye injury and treatment is for 5 days only.				
Note: Indications marked with * are unapproved indications.				
PAROMOMYCIN – Special Authority see SA1689 below – Retail pharmacy				
Cap 250 mg	126.00	16	✓	Humatin ^{S29}
➔ SA1689 Special Authority for Subsidy				
Initial application only from an infectious disease specialist, clinical microbiologist or gastroenterologist. Approvals valid for 1 month for applications meeting the following criteria:				
Either:				
1 Patient has confirmed cryptosporidium infection; or				
2 For the eradication of Entamoeba histolytica carriage.				
Renewal only from an infectious disease specialist, clinical microbiologist or gastroenterologist. Approvals valid for 1 month for applications meeting the following criteria:				
Either:				
1 Patient has confirmed cryptosporidium infection; or				
2 For the eradication of Entamoeba histolytica carriage.				
PYRIMETHAMINE – Special Authority see SA1328 below – Retail pharmacy				
Tab 25 mg	48.00	30	✓	Daraprim ^{S29}
➔ SA1328 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:				
Any of the following:				
1 For the treatment of toxoplasmosis in patients with HIV for a period of 3 months; or				
2 For pregnant patients for the term of the pregnancy; or				
3 For infants with congenital toxoplasmosis until 12 months of age.				
SODIUM FUSIDATE [FUSIDIC ACID]				
Tab 250 mg	67.85	36	✓	Fucidin
SULFADIAZINE SODIUM – Special Authority see SA1331 below – Retail pharmacy				
Tab 500 mg	543.20	56	✓	Wockhardt ^{S29}
➔ SA1331 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:				
Any of the following:				
1 For the treatment of toxoplasmosis in patients with HIV for a period of 3 months; or				
2 For pregnant patients for the term of the pregnancy; or				
3 For infants with congenital toxoplasmosis until 12 months of age.				
TOBRAMYCIN				
Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement	18.50	5	✓	Tobramycin Mylan
Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.				
Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsement.....	395.00	56 dose	✓	Tobramycin BNM
a) Wastage claimable				
b) Only if prescribed for a cystic fibrosis patient and the prescription is endorsed accordingly.				
TRIMETHOPRIM				
* Tab 300 mg – Up to 30 tab available on a PSO	18.55	50	✓	TMP

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOXAZOLE]				
* Tab trimethoprim 80 mg and sulphamethoxazole 400 mg – Up to 30 tab available on a PSO.....	64.80	500	✓	Trisul
* Oral liq 8 mg sulphamethoxazole 40 mg per ml – Up to 200 ml available on a PSO.....	2.97	100 ml	✓	Deprim
VANCOMYCIN – Subsidy by endorsement				
Only if prescribed for a dialysis or cystic fibrosis patient or for prophylaxis of endocarditis or for treatment of Clostridium difficile following metronidazole failure and the prescription is endorsed accordingly.				
Inj 500 mg vial	2.35	1	✓	Mylan

Antifungals

- a) For topical antifungals refer to DERMATOLOGICALS, [page 62](#)
b) For topical antifungals refer to GENITO URINARY, [page 75](#)

FLUCONAZOLE				
Cap 50 mg	2.75	28	✓	Mylan
Cap 150 mg	0.65	1	✓	Mylan
Cap 200 mg	12.89	28	✓	Mylan
Powder for oral suspension 10 mg per ml – Special Authority see SA1359 below – Retail pharmacy.....	109.34	35 ml	✓	Diflucan
Wastage claimable				

►SA1359 Special Authority for Subsidy

Initial application — (Systemic candidiasis) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient requires prophylaxis for, or treatment of systemic candidiasis; and
- 2 Patient is unable to swallow capsules.

Initial application — (Immunocompromised) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient is immunocompromised; and
- 2 Patient is at moderate to high risk of invasive fungal infection; and
- 3 Patient is unable to swallow capsules.

Renewal — (Systemic candidiasis) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient requires prophylaxis for, or treatment of systemic candidiasis; and
- 2 Patient is unable to swallow capsules.

Renewal — (Immunocompromised) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient remains immunocompromised; and
- 2 Patient remains at moderate to high risk of invasive fungal infection; and
- 3 Patient is unable to swallow capsules.

ITRACONAZOLE				
Cap 100 mg	4.27	15	✓	Itrazole
Oral liq 10 mg per ml – Special Authority see SA1322 on the next page – Retail pharmacy.....	141.80	150 ml OP	✓	Sporanox

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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►SA1322 Special Authority for Subsidy

Initial application only from an infectious disease specialist, clinical microbiologist, clinical immunologist or any relevant practitioner on the recommendation of a infectious disease physician, clinical microbiologist or clinical immunologist. Approvals valid for 6 months where the patient has a congenital immune deficiency.

Renewal from any relevant practitioner. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefitting from the treatment.

KETOCONAZOLE

Tab 200 mg – PCT	CBS	30	✓ Link Healthcare S29
		100	✓ Nizoral S29
			✓ Strides Shasun S29

NYSTATIN

Tab 500,000 u	14.16 (17.09)	50	Nilstat
Cap 500,000 u	12.81 (15.47)	50	Nilstat

POSACONAZOLE – Special Authority see SA1285 below – Retail pharmacy

Tab modified-release 100 mg	869.86	24	✓ Noxafil
Oral liq 40 mg per ml	761.13	105 ml OP	✓ Noxafil

►SA1285 Special Authority for Subsidy

Initial application only from a haematologist or infectious disease specialist. Approvals valid for 6 weeks for applications meeting the following criteria:

Either:

- 1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation chemotherapy; or
- 2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppressive therapy*.

Renewal only from a haematologist or infectious disease specialist. Approvals valid for 6 weeks for applications meeting the following criteria:

Either:

- 1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation therapy; or
- 2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppression* and requires on going posaconazole treatment.

Note: * Graft versus host disease (GVHD) on significant immunosuppression is defined as acute GVHD, grade II to IV, or extensive chronic GVHD, or if they were being treated with intensive immunosuppressive therapy consisting of either high-dose corticosteroids (1 mg or greater per kilogram of body weight per day for patients with acute GVHD or 0.8 mg or greater per kilogram every other day for patients with chronic GVHD), antithymocyte globulin, or a combination of two or more immunosuppressive agents or types of treatment.

TERBINAFINE

* Tab 250 mg	8.15	84	✓ Deolate
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VORICONAZOLE – Special Authority see SA1273 on the next page – Retail pharmacy

Tab 50 mg	91.00	56	✓ Vttack
Tab 200 mg	350.00	56	✓ Vttack
Powder for oral suspension 40 mg per ml – Wastage claimable	1,523.22	70 ml	✓ Vfend

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1273 Special Authority for Subsidy

Initial application — (invasive fungal infection) only from a haematologist, infectious disease specialist or clinical microbiologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient is immunocompromised; and
- 2 Applicant is part of a multidisciplinary team including an infectious disease specialist; and
- 3 Any of the following:
 - 3.1 Patient has proven or probable invasive aspergillus infection; or
 - 3.2 Patient has possible invasive aspergillus infection; or
 - 3.3 Patient has fluconazole resistant candidiasis; or
 - 3.4 Patient has mould strain such as *Fusarium* spp. and *Scedosporium* spp.

Renewal — (invasive fungal infection) only from a haematologist, infectious disease specialist or clinical microbiologist.

Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient is immunocompromised; and
- 2 Applicant is part of a multidisciplinary team including an infectious disease specialist; and
- 3 Any of the following:
 - 3.1 Patient continues to require treatment for proven or probable invasive aspergillus infection; or
 - 3.2 Patient continues to require treatment for possible invasive aspergillus infection; or
 - 3.3 Patient has fluconazole resistant candidiasis; or
 - 3.4 Patient has mould strain such as *Fusarium* spp. and *Scedosporium* spp.

Antimalarials

PRIMAQUINE – Special Authority see [SA1684 below](#) – Retail pharmacy

Tab 15 mg	400.00	100	✓ Sanofi Primaquine ^{S29}
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►SA1684 Special Authority for Subsidy

Initial application only from an infectious disease specialist or clinical microbiologist. Approvals valid for 1 month for applications meeting the following criteria:

Both:

- 1 The patient has vivax or ovale malaria; and
- 2 Primaquine is to be given for a maximum of 21 days.

Renewal only from an infectious disease specialist or clinical microbiologist. Approvals valid for 1 month for applications meeting the following criteria:

Both:

- 1 The patient has relapsed vivax or ovale malaria; and
- 2 Primaquine is to be given for a maximum of 21 days.

Antitrichomonal Agents

METRONIDAZOLE

Tab 200 mg – Up to 30 tab available on a PSO	33.15	250	✓ Metrogyl
Tab 400 mg – Up to 15 tab available on a PSO	5.23	21	✓ Metrogyl
Oral liq benzoate 200 mg per 5 ml	25.00	100 ml	✓ Flagyl-S
Suppos 500 mg	24.48	10	✓ Flagyl

ORNIDAZOLE

Tab 500 mg	36.16	10	✓ Arrow-Ornidazole
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

Antituberculotics and Antileptotics

Note: There is no co-payment charge for all pharmaceuticals listed in the Antituberculotics and Antileptotics group regardless of immigration status.

CLOFAZIMINE – Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist.

* Cap 50 mg 442.00 100 ✓ **Lamprene** \$29

CYCLOSERINE – Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician.

Cap 250 mg 344.00 60 ✓ **Cyclorin** \$29

DAPSONE – Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist

Tab 25 mg 268.50 100 ✓ **Dapsone**

Tab 100 mg 329.50 100 ✓ **Dapsone**

ETHAMBUTOL HYDROCHLORIDE – Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician

Tab 100 mg 85.73 100 ✓ **EMB Fatol** \$29

Tab 400 mg 49.34 56 ✓ **Myambutol** \$29

ISONIAZID – Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician, paediatrician, clinical microbiologist, dermatologist or public health physician

* Tab 100 mg 23.00 100 ✓ **PSM**

ISONIAZID WITH RIFAMPICIN – Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician, paediatrician, clinical microbiologist, dermatologist or public health physician

* Tab 100 mg with rifampicin 150 mg 89.82 100 ✓ **Rifinah**

* Tab 150 mg with rifampicin 300 mg 179.13 100 ✓ **Rifinah**

PARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease specialist, clinical microbiologist or respiratory physician

Grans for oral liq 4 g sachet 280.00 30 ✓ **Paser** \$29

PROTONAMIDE – Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease specialist, clinical microbiologist or respiratory physician

Tab 250 mg 305.00 100 ✓ **Peteha** \$29

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

INFECTIONS - AGENTS FOR SYSTEMIC USE

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PYRAZINAMIDE – Retail pharmacy-Specialist				
a) No patient co-payment payable				
b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician				
* Tab 500 mg	64.95	100	✓	AFT-Pyrazinamide
RIFABUTIN – Retail pharmacy-Specialist				
a) No patient co-payment payable				
b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, respiratory physician or gastroenterologist				
* Cap 150 mg	299.75	30	✓	Mycobutin
RIFAMPICIN – Subsidy by endorsement				
a) No patient co-payment payable				
b) For confirmed recurrent <i>Staphylococcus aureus</i> infection in combination with other effective anti-staphylococcal antimicrobial based on susceptibilities and the prescription is endorsed accordingly; can be waived by endorsement - Retail pharmacy - Specialist. Specialist must be an internal medicine physician, clinical microbiologist, dermatologist, paediatrician, or public health physician.				
* Cap 150 mg	58.54	100	✓	Rifadin
* Cap 300 mg	122.06	100	✓	Rifadin
* Oral liq 100 mg per 5 ml	12.60	60 ml	✓	Rifadin

Antivirals

For eye preparations refer to Eye Preparations, Anti-Infective Preparations, [page 239](#)

Hepatitis B Treatment

ENTECAVIR				
* Tab 0.5 mg	52.00	30	✓	Entecavir Sandoz
LAMIVUDINE – Special Authority see SA1685 below – Retail pharmacy				
Tab 100 mg	6.95	28	✓	Zetlam
Oral liq 5 mg per ml	270.00	240 ml OP	✓	Zeffix

►SA1685 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 1 year where used for the treatment or prevention of hepatitis B.

Renewal from any relevant practitioner. Approvals valid for 2 years where used for the treatment or prevention of hepatitis B.

TENOFOVIR DISOPROXIL

Tenofovir disoproxil prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals for the purposes of Special Authority SA2139., [page 103](#)

* Tab 245 mg (300 mg as a maleate)	15.00	30	✓	Tenofovir Disoproxil Mylan
Tenofovir Disoproxil Mylan to be Principal Supply on 1 December 2022				
* Tab 245 mg (300.6 mg as a succinate)	38.10	30	✓	Tenofovir Disoproxil Teva

(Tenofovir Disoproxil Teva Tab 245 mg (300.6 mg as a succinate) to be delisted 1 December 2022)

Herpesvirus Treatments

ACICLOVIR				
* Tab dispersible 200 mg	1.60	25	✓	Lovir
* Tab dispersible 400 mg	5.38	56	✓	Lovir
* Tab dispersible 800 mg	5.98	35	✓	Lovir

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
VALACICLOVIR				
Tab 500 mg	6.50	30	✓	Vaclovir
Tab 1,000 mg	13.76	30	✓	Vaclovir
VALGANCICLOVIR – Special Authority see SA1993 below – Retail pharmacy				
Tab 450 mg	132.00	60	✓	Valganciclovir Mylan

► **SA1993** Special Authority for Subsidy

Initial application — (transplant cytomegalovirus prophylaxis) only from a relevant specialist. Approvals valid for 3 months where the patient has undergone a solid organ transplant and requires valganciclovir for CMV prophylaxis.

Renewal — (transplant cytomegalovirus prophylaxis) only from a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Patient has undergone a solid organ transplant and received anti-thymocyte globulin and requires valganciclovir therapy for CMV prophylaxis; and
 - 1.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following anti-thymocyte globulin; or
- 2 Both:
 - 2.1 Patient has received pulse methylprednisolone for acute rejection and requires further valganciclovir therapy for CMV prophylaxis; and
 - 2.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following pulse methylprednisolone.

Initial application — (cytomegalovirus prophylaxis following anti-thymocyte globulin) only from a relevant specialist.

Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient has undergone a solid organ transplant and received valganciclovir under Special Authority more than 2 years ago (27 months); and
- 2 Patient has received anti-thymocyte globulin and requires valganciclovir for CMV prophylaxis.

Renewal — (cytomegalovirus prophylaxis following anti-thymocyte globulin) only from a relevant specialist. Approvals valid for 3 months where the patient has received a further course of anti-thymocyte globulin and requires valganciclovir for CMV prophylaxis.

Initial application — (Lung transplant cytomegalovirus prophylaxis) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has undergone a lung transplant; and
- 2 Either:
 - 2.1 The donor was cytomegalovirus positive and the patient is cytomegalovirus negative; or
 - 2.2 The recipient is cytomegalovirus positive; and
- 3 Patient has a high risk of CMV disease.

Initial application — (Cytomegalovirus in immunocompromised patients) only from a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient is immunocompromised; and
- 2 Any of the following:
 - 2.1 Patient has cytomegalovirus syndrome or tissue invasive disease; or
 - 2.2 Patient has rapidly rising plasma CMV DNA in absence of disease; or
 - 2.3 Patient has cytomegalovirus retinitis.

Renewal — (Cytomegalovirus in immunocompromised patients) only from a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

continued...

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 1 Patient is immunocompromised; and
- 2 Any of the following:
 - 2.1 Patient has cytomegalovirus syndrome or tissue invasive disease; or
 - 2.2 Patient has rapidly rising plasma CMV DNA in absence of disease; or
 - 2.3 Patient has cytomegalovirus retinitis.

Note: for the purpose of this Special Authority "immunocompromised" includes transplant recipients, patients with immunosuppressive diseases (e.g. HIV) or those receiving immunosuppressive treatment for other conditions.

Hepatitis C Treatment

GLECAPREVIR WITH PIBRENTASVIR – [Xpharm]

Note the supply of treatment is via Pharmac's approved direct distribution supply. Further details can be found on Pharmac's website <https://pharmac.govt.nz/maviret>

Tab 100 mg with pibrentasvir 40 mg	24,750.00	84 OP	✓ Maviret
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LEDIPASVIR WITH SOFOSBUVIR – [Xpharm] – Special Authority see [SA1605 below](#)

No patient co-payment payable

Tab 90 mg with sofosbuvir 400 mg.....	24,363.46	28	✓ Harvoni
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➔ [SA1605](#) Special Authority for Subsidy

Special Authority approved by the Hepatitis C Treatment Panel (HepCTP)

Notes: By application to the Hepatitis C Treatment Panel (HepCTP).

Applications will be considered by HepCTP and approved subject to confirmation of eligibility.

Application details may be obtained from Pharmac's website <http://www.pharmac.govt.nz/maviret> or:

The Coordinator, Hepatitis C Treatment Panel

Pharmac, PO Box 10-254, WELLINGTON Tel: (04) 460 4990,

Email: hepcpanel@pharmac.govt.nz

HIV Prophylaxis and Treatment

EMTRICITABINE WITH TENOFOVIR DISOPROXIL – Subsidy by endorsement; can be waived by Special Authority see [SA2138 on the next page](#)

Endorsement for treatment of HIV: Prescription is deemed to be endorsed if emtricitabine with tenofovir disoproxil is co-prescribed with another antiretroviral subsidised under Special Authority SA2139 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.

Note: Emtricitabine with tenofovir disoproxil prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals, and counts as two antiretroviral medications, for the purposes of Special Authority SA2139, [page 103](#) There is an approval process to become a named specialist to prescribe antiretroviral therapy in New Zealand. Further information is available on the Pharmac website.

* Tab 200 mg with tenofovir disoproxil 245 mg (300 mg as a maleate).....	15.45	30	✓ Tenofovir Disoproxil Emtricitabine Mylan
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Tenofovir Disoproxil Emtricitabine Mylan to be Principal Supply on 1 December 2022

* Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate)	61.15	30	✓ Teva
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(Teva Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) to be delisted 1 December 2022)

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA2138 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria:
Both:

- 1 Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion; and
- 2 The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate.

Notes: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines:

<https://ashm.org.au/HIV/PrEP/>

Renewal from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion; and
- 2 The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate.

Notes: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines:

<https://ashm.org.au/HIV/PrEP/>

COVID-19 Treatments

MOLNUPIRAVIR – [Xpharm] – Subsidy by endorsement

- a) No patient co-payment payable
- b) Treatment is funded only if patient meets access criteria for oral antiviral COVID-19 treatments (as on [Pharmac's website](#)) and has been endorsed accordingly by the prescriber. The supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability.

Cap 200 mg 0.00 40 ✓ **Lagevrio**

NIRMATRELVIR WITH RITONAVIR – [Xpharm] – Subsidy by endorsement

- a) No patient co-payment payable
- b) Treatment is funded only if patient meets access criteria for oral antiviral COVID-19 treatments (as on [Pharmac's website](#)) and has been endorsed accordingly by the prescriber. The supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability.

Tab 150 mg with ritonavir 100 mg 0.00 30 ✓ **Paxlovid**

Antiretrovirals

►SA2139 Special Authority for Subsidy

Initial application — (Confirmed HIV) only from a named specialist. Approvals valid without further renewal unless notified where the patient has confirmed HIV infection.

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Renewal — (Confirmed HIV) only from a named specialist. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (Prevention of maternal transmission) only from a named specialist. Approvals valid for 1 year for applications meeting the following criteria:

Either:

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 1 Prevention of maternal foetal transmission; or
- 2 Treatment of the newborn for up to eight weeks.

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Some antiretrovirals are unapproved or contraindicated for this indication. Practitioners prescribing these medications should exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of a Pharmaceutical for an indication for which it is not approved or contraindicated.

Initial application — (post-exposure prophylaxis following exposure to HIV) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Treatment course to be initiated within 72 hours post exposure; and
- 2 Any of the following:
 - 2.1 Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV positive person with an unknown or detectable viral load greater than 200 copies per ml; or
 - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
 - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required; or
 - 2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (<https://www.ashm.org.au/hiv/hiv-management/pep/>).

Renewal — (second or subsequent post-exposure prophylaxis) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Treatment course to be initiated within 72 hours post exposure; and
- 2 Any of the following:
 - 2.1 Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV positive person with an unknown or detectable viral load greater than 200 copies per ml; or
 - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
 - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required; or
 - 2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.

Initial application — (Percutaneous exposure) only from a named specialist. Approvals valid for 6 weeks where the patient has percutaneous exposure to blood known to be HIV positive.

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Renewal — (Second or subsequent percutaneous exposure) only from a named specialist. Approvals valid for 6 weeks where the patient has percutaneous exposure to blood known to be HIV positive.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Non-nucleosides Reverse Transcriptase Inhibitors				
EFAVIRENZ – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 200 mg	190.15	90	✓	Stocrin
Tab 600 mg	63.38	30	✓	Stocrin
ETRAVIRINE – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 200 mg	770.00	60	✓	Intelence
NEVIRAPINE – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 200 mg	84.00	60	✓	<u>Nevirapine</u>
Oral suspension 10 mg per ml.....	203.55	240 ml OP	✓	<u>Alphapharm</u> Viramune Suspension

Nucleosides Reverse Transcriptase Inhibitors				
ABACAIR SULPHATE – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 300 mg	180.00	60	✓	Ziagen
Oral liq 20 mg per ml	256.31	240 ml OP	✓	Ziagen
ABACAIR SULPHATE WITH LAMIVUDINE – Special Authority see SA2139 on page 103 – Retail pharmacy				
Note: abacavir with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority.				
Tab 600 mg with lamivudine 300 mg.....	63.00	30	✓	Kivexa
EFAVIRENZ WITH ETRICITABINE AND TENOFOVIR DISOPROXIL – Special Authority see SA2139 on page 103 – Retail pharmacy				
Note: Efavirenz with emtricitabine and tenofovir disoproxil counts as three anti-retroviral medications for the purposes of the anti-retroviral Special Authority				
Tab 600 mg with emtricitabine 200 mg and tenofovir disoproxil 245 mg (300 mg as a maleate).....	106.88	30	✓	Mylan
EMTRICITABINE – Special Authority see SA2139 on page 103 – Retail pharmacy				
Cap 200 mg	307.20	30	✓	Emtriva
LAMIVUDINE – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 150 mg	84.50	60	✓	<u>Lamivudine</u>
Oral liq 10 mg per ml	102.50	240 ml OP	✓	<u>Alphapharm</u> 3TC
ZIDOVUDINE [AZT] – Special Authority see SA2139 on page 103 – Retail pharmacy				
Cap 100 mg	152.25	100	✓	Retrovir
Oral liq 10 mg per ml	30.45	200 ml OP	✓	Retrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority see SA2139 on page 103 – Retail pharmacy				
Note: zidovudine [AZT] with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority.				
Tab 300 mg with lamivudine 150 mg.....	33.00	60	✓	Alphapharm

Protease Inhibitors				
ATAZANAVIR SULPHATE – Special Authority see SA2139 on page 103 – Retail pharmacy				
Cap 150 mg	141.68	60	✓	Teva
Cap 200 mg	188.91	60	✓	Teva
DARUNAVIR – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 400 mg	132.00	60	✓	<u>Darunavir Mylan</u>
Tab 600 mg	196.65	60	✓	<u>Darunavir Mylan</u>

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LOPINAVIR WITH RITONAVIR – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 100 mg with ritonavir 25 mg	150.00	60	✓	Lopinavir/Ritonavir Mylan
Tab 200 mg with ritonavir 50 mg	295.00	120	✓	Lopinavir/Ritonavir Mylan
Oral liq 80 mg with ritonavir 20 mg per ml	735.00	300 ml OP	✓	Kaletra
RITONAVIR – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 100 mg	43.31	30	✓	Norvir

Strand Transfer Inhibitors

DOLUTEGRAVIR – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 50 mg	1,090.00	30	✓	Tivicay
RALTEGRAVIR POTASSIUM – Special Authority see SA2139 on page 103 – Retail pharmacy				
Tab 400 mg	1,090.00	60	✓	Isetress
Tab 600 mg	1,090.00	60	✓	Isetress HD

Immune Modulators

Guidelines for the use of interferon in the treatment of hepatitis C:

Physicians considering treatment of patients with hepatitis C should discuss cases with a gastroenterologist or an infectious disease physician. All subjects undergoing treatment require careful monitoring for side effects.

Patients should be otherwise fit.

Hepatocellular carcinoma should be excluded by ultrasound examination and alpha-fetoprotein level.

Criteria for Treatment

- 1) Diagnosis
 - Anti-HCV positive on at least two occasions with a positive PCR for HCV-RNA and preferably confirmed by a supplementary RIBA test; or
 - PCR-RNA positive for HCV on at least 2 occasions if antibody negative; or
 - Anti-HCV positive on at least two occasions with a positive supplementary RIBA test with a negative PCR for HCV RNA but with a liver biopsy consistent with 2(b) following.

Exclusion Criteria

- 1) Autoimmune liver disease. (Interferon may exacerbate autoimmune liver disease as well as other autoimmune diseases such as thyroid disease).
- 2) Pregnancy.
- 3) Neutropenia ($< 2.0 \times 10^9$) and/or thrombocytopenia.
- 4) Continuing alcohol abuse and/or continuing intravenous drug users.

Dosage

The current recommended dosage is 3 million units of interferon alfa-2a or interferon alfa-2b administered subcutaneously 3 times a week for 52 weeks (twelve months)

Exit Criteria

The patient's response to interferon treatment should be reviewed at either three or four months. Interferon treatment should be discontinued in patients who do not show a substantial reduction (50%) in their mean pre-treatment ALT level at this stage.

PEGYLATED INTERFERON ALFA-2A – Special Authority see [SA2034 on the next page](#) – Retail pharmacy

- a) See prescribing guideline [above](#)
- b) Note: Pharmac will consider funding ribavirin for the small group of patients who have a clinical need for ribavirin and meet Special Authority criteria. Please contact the Hepatitis C Coordinator at Pharmac on 0800-023-588 option 4.

Inj 180 mcg prefilled syringe.....	500.00	4	✓	Pegasys
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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►SA2034 Special Authority for Subsidy

Initial application — (chronic hepatitis C - genotype 1, 4, 5 or 6 infection or co-infection with HIV or genotype 2 or 3 post liver transplant) from any specialist. Approvals valid for 18 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection; or
 - 1.2 Patient has chronic hepatitis C and is co-infected with HIV; or
 - 1.3 Patient has chronic hepatitis C genotype 2 or 3 and has received a liver transplant; and
- 2 Maximum of 48 weeks therapy.

Notes:

- Consider stopping treatment if there is absence of a virological response (defined as at least a 2-log reduction in viral load) following 12 weeks of treatment since this is predictive of treatment failure.
- Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (less than 50IU/ml) AND Baseline serum HCV RNA is less than 400,000IU/ml

Renewal — (Chronic hepatitis C - genotype 1 infection) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Patient has chronic hepatitis C, genotype 1; and
- 2 Patient has had previous treatment with pegylated interferon and ribavirin; and
- 3 Either:
 - 3.1 Patient has responder relapsed; or
 - 3.2 Patient was a partial responder; and
- 4 Patient is to be treated in combination with boceprevir; and
- 5 Maximum of 48 weeks therapy.

Initial application — (Chronic Hepatitis C - genotype 1 infection treatment more than 4 years prior) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Patient has chronic hepatitis C, genotype 1; and
- 2 Patient has had previous treatment with pegylated interferon and ribavirin; and
- 3 Any of the following:
 - 3.1 Patient has responder relapsed; or
 - 3.2 Patient was a partial responder; or
 - 3.3 Patient received interferon treatment prior to 2004; and
- 4 Patient is to be treated in combination with boceprevir; and
- 5 Maximum of 48 weeks therapy.

Initial application — (chronic hepatitis C - genotype 2 or 3 infection without co-infection with HIV) from any specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient has chronic hepatitis C, genotype 2 or 3 infection; and
- 2 Maximum of 6 months therapy.

Initial application — (Hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
- 2 Patient is Hepatitis B treatment-naïve; and
- 3 ALT > 2 times Upper Limit of Normal; and

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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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- 4 HBV DNA < 10 log10 IU/ml; and
- 5 Either:
 - 5.1 HBeAg positive; or
 - 5.2 serum HBV DNA greater than or equal to 2,000 units/ml and significant fibrosis (Metavir Stage F2 or greater or moderate fibrosis); and
- 6 Compensated liver disease; and
- 7 No continuing alcohol abuse or intravenous drug use; and
- 8 Not co-infected with HCV, HIV or HDV; and
- 9 Neither ALT nor AST > 10 times upper limit of normal; and
- 10 No history of hypersensitivity or contraindications to pegylated interferon; and
- 11 Maximum of 48 weeks therapy.

Initial application — (myeloproliferative disorder or cutaneous T cell lymphoma) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

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

Renewal — (myeloproliferative disorder or cutaneous T cell lymphoma) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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

Notes: Indications marked with * are unapproved indications.

- Approved dose is 180 mcg once weekly.
- The recommended dose of Pegylated Interferon alfa-2a is 180 mcg once weekly.
- In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon-alfa 2a dose should be reduced to 135 mcg once weekly.
- In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet guidelines.
- Pegylated Interferon-alfa 2a is not approved for use in children.

Initial application — (post-allogeneic bone marrow transplant) from any relevant practitioner. Approvals valid for 3 months where patient has received an allogeneic bone marrow transplant* and has evidence of disease relapse.

Renewal — (post-allogeneic bone marrow transplant) from any relevant practitioner. Approvals valid for 3 months where patient is responding and ongoing treatment remains appropriate.

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Note: Indications marked with * are unapproved indications.

Urinary Tract Infections

METHENAMINE (HEXAMINE) HIPPURATE

* Tab 1 g19.95 100 ✓ **Hiprex**

NITROFURANTOIN

* Tab 50 mg – Up to 30 tab available on a PSO22.20 100 ✓ **Nifuran**
Nifuran to be Principal Supply on 1 December 2022

* Tab 100 mg37.50 100 ✓ **Nifuran**
Nifuran to be Principal Supply on 1 December 2022

* Cap modified-release 100 mg – Up to 15 cap available on a
PSO86.40 100 ✓ **Macrobid**

NORFLOXACIN

Tab 400 mg – Subsidy by endorsement.....245.00 100 ✓ **Arrow-Norfloxacin**

Only if prescribed for a patient with an uncomplicated urinary tract infection that is unresponsive to a first line agent or with proven resistance to first line agents and the prescription is endorsed accordingly.

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Anticholinesterases

NEOSTIGMINE METILSULFATE				
Inj 2.5 mg per ml, 1 ml ampoule	33.81	10	✓	<u>Max Health</u>
PYRIDOSTIGMINE BROMIDE				
▲ Tab 60 mg	45.79	100	✓	<u>Mestinon</u>

Non-Steroidal Anti-Inflammatory Drugs

DICLOFENAC SODIUM				
* Tab EC 25 mg	1.99	50	✓	<u>Diclofenac Sandoz</u>
* Tab 50 mg dispersible	1.50	20	✓	<u>Voltaren D</u>
* Tab EC 50 mg	1.99	50	✓	<u>Diclofenac Sandoz</u>
* Tab long-acting 75 mg	19.60	100	✓	<u>Voltaren SR</u>
* Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a PSO	13.20	5	✓	<u>Voltaren</u>
* Suppos 12.5 mg	2.04	10	✓	<u>Voltaren</u>
* Suppos 25 mg	2.44	10	✓	<u>Voltaren</u>
* Suppos 50 mg – Up to 10 supp available on a PSO	4.22	10	✓	<u>Voltaren</u>
* Suppos 100 mg	7.00	10	✓	<u>Voltaren</u>
IBUPROFEN				
* Tab 200 mg	21.40	1,000	✓	<u>Relieve</u>
* Tab long-acting 800 mg	3.05	30	✓	<u>Brufen SR</u>
* Oral liq 20 mg per ml	2.25	200 ml	✓	<u>Ethics</u>
	11.29		✓	<u>Fenpaed 100 mg per 5 ml</u>
KETOPROFEN				
* Cap long-acting 200 mg	12.07	28	✓	<u>Oruvail SR</u>
MEFENAMIC ACID				
* Cap 250 mg	1.25	50		
	(9.16)			Ponstan
	0.50	20		
	(7.50)			Ponstan
NAPROXEN				
* Tab 250 mg	32.69	500	✓	<u>Noflam 250</u>
* Tab 500 mg	28.71	250	✓	<u>Noflam 500</u>
* Tab long-acting 750 mg	6.47	28	✓	<u>Naprosyn SR 750</u>
* Tab long-acting 1 g	8.62	28	✓	<u>Naprosyn SR 1000</u>
TENOXICAM				
* Tab 20 mg	18.50	100	✓	<u>Tilcotil</u>
* Inj 20 mg vial	9.95	1	✓	<u>AFT</u>

NSAIDs Other

CELECOXIB				
Cap 100 mg	3.45	60	✓	<u>Celebrex</u>
			✓	<u>Celecoxib Pfizer</u>
Cap 200 mg	3.20	30	✓	<u>Celebrex</u>
			✓	<u>Celecoxib Pfizer</u>

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

Topical Products for Joint and Muscular Pain

CAPSAICIN

Crm 0.025% – Special Authority see [SA1289 below](#) – Retail

pharmacy.....	9.75	45 g OP	✓ Zostrix
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➤SA1289 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has osteoarthritis that is not responsive to paracetamol and oral non-steroidal anti-inflammatories are contraindicated.

Antirheumatoid Agents

HYDROXYCHLOROQUINE – Subsidy by endorsement

Subsidised only if prescribed for rheumatoid arthritis, systemic or discoid lupus erythematosus, malaria treatment or suppression, relevant dermatological conditions (cutaneous forms of lupus and lichen planus, cutaneous vasculitides and mucosal ulceration)*, sarcoidosis (pulmonary and non-pulmonary)*, and the prescription is endorsed accordingly.

Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of hydroxychloroquine. Note: Indication marked with a * is an unapproved indication.

* Tab 200 mg	8.78	100	✓ Plaquenil
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LEFLUNOMIDE

Tab 10 mg	6.00	30	✓ Arava
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Tab 20 mg	6.00	30	✓ Arava
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PENICILLAMINE

Tab 125 mg	67.23	100	✓ D-Penamine
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Tab 250 mg	110.12	100	✓ D-Penamine
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Drugs Affecting Bone Metabolism

Alendronate for Osteoporosis

ALENDRONATE SODIUM

* Tab 70 mg	2.44	4	✓ Fosamax
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ALENDRONATE SODIUM WITH COLECALCIFEROL

* Tab 70 mg with colecalciferol 5,600 iu	1.51	4	✓ Fosamax Plus
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Other Treatments

DENOSUMAB – Special Authority see [SA1777 below](#) – Retail pharmacy

Inj 60 mg prefilled syringe.....	326.00	1	✓ Prolia
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➤SA1777 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 The patient has severe, established osteoporosis; and
- 2 Either:
 - 2.1 The patient is female and postmenopausal; or
 - 2.2 The patient is male or non-binary; and
- 3 Any of the following:
 - 3.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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- (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
- 3.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons; or
- 3.3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 3.4 Documented T-Score less than or equal to -3.0 (see Note); or
- 3.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
- 3.6 Patient has had a Special Authority approval for alendronate (Underlying cause - Osteoporosis) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 4 Zoledronic acid is contraindicated because the patient's creatinine clearance is less than 35 mL/min; and
- 5 The patient has experienced at least one symptomatic new fracture after at least 12 months' continuous therapy with a funded antiresorptive agent at adequate doses (see Notes); and
- 6 The patient must not receive concomitant treatment with any other funded antiresorptive agent for this condition or teriparatide.

Notes:

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable
- b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with denosumab
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less
- d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body
- e) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: risedronate sodium tab 35 mg once weekly; alendronate sodium tab 70 mg or tab 70 mg with cholecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy

PAMIDRONATE DISODIUM

Inj 3 mg per ml, 10 ml vial.....	27.53	1	✓ Pamisol
Inj 6 mg per ml, 10 ml vial.....	74.67	1	✓ Pamisol
Inj 9 mg per ml, 10 ml vial.....	79.95	1	✓ Pamisol

RALOXIFENE HYDROCHLORIDE – Special Authority see [SA1779 below](#) – Retail pharmacy

* Tab 60 mg	53.76	28	✓ Evista
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►SA1779 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Notes); or

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 4 Documented T-Score less than or equal to -3.0 (see Notes); or
- 5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Notes); or
- 6 Patient has had a Special Authority approval for zoledronic acid (Underlying cause – Osteoporosis) or has had a Special Authority approval for alendronate (Underlying cause - Osteoporosis) prior to 1 February 2019.

Notes:

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for raloxifene funding.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

RISEDRONATE SODIUM

Tab 35 mg 3.10 4 ✓ Risedronate Sandoz

TERIPARATIDE – Special Authority see [SA1139 below](#) – Retail pharmacy

Inj 250 mcg per ml, 2.4 ml 490.00 1 ✓ Forteo

► [SA1139](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe, established osteoporosis; and
- 2 The patient has a documented T-score less than or equal to -3.0 (see Notes); and
- 3 The patient has had two or more fractures due to minimal trauma; and
- 4 The patient has experienced at least one symptomatic new fracture after at least 12 months' continuous therapy with a funded antiresorptive agent at adequate doses (see Notes).

Notes:

- a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable
- b) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: alendronate sodium tab 70 mg or tab 70 mg with colecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy.
- c) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
- d) A maximum of 18 months of treatment (18 cartridges) will be subsidised.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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ZOLEDRONIC ACID

Inj 0.05 mg per ml, 100 ml, vial – Special Authority see

SA2110 below – Retail pharmacy 60.00 100 ml OP ✓ **Aclasta**

►SA2110 Special Authority for Subsidy

Initial application — (Paget's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Paget's disease; and
- 2 Any of the following:
 - 2.1 Bone or articular pain; or
 - 2.2 Bone deformity; or
 - 2.3 Bone, articular or neurological complications; or
 - 2.4 Asymptomatic disease, but risk of complications; or
 - 2.5 Preparation for orthopaedic surgery; and
- 3 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

Initial application — (Underlying cause - Osteoporosis) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
 - 1.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
 - 1.3 History of two significant osteoporotic fractures demonstrated radiologically; or
 - 1.4 Documented T-Score less than or equal to -3.0 (see Note); or
 - 1.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
 - 1.6 Patient has had a Special Authority approval for alendronate (Underlying cause - Osteoporosis) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

Initial application — (Underlying cause - glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is receiving systemic glucocorticosteroid therapy (greater than or equal to 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- 2 Any of the following:
 - 2.1 The patient has documented BMD greater than or equal to 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -1.5) (see Note); or
 - 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
 - 2.3 The patient has had a Special Authority approval for alendronate (Underlying cause - glucocorticosteroid therapy) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 3 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

Renewal — (Paget's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Any of the following:

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 1.1 The patient has relapsed (based on increases in serum alkaline phosphatase); or
- 1.2 The patient's serum alkaline phosphatase has not normalised following previous treatment with zoledronic acid; or
- 1.3 Symptomatic disease (prescriber determined); and

2 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

The patient must not have had more than 1 prior approval in the last 12 months.

Renewal — (Underlying cause was, and remains, glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The patient is continuing systemic glucocorticosteroid therapy (greater than or equal to 5 mg per day prednisone equivalents); and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

The patient must not have had more than 1 prior approval in the last 12 months.

Renewal — (Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause - osteoporosis' criteria) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
 - 1.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
 - 1.3 History of two significant osteoporotic fractures demonstrated radiologically; or
 - 1.4 Documented T-Score less than or equal to -3.0 (see Note); or
 - 1.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
 - 1.6 The patient has had a Special Authority approval for alendronate (Underlying was glucocorticosteroid therapy but patient now meets the 'Underlying cause - Osteoporosis' criteria) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

Initial application — (spinal cord injury*) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Patient has experienced an acute traumatic spinal cord injury in the last six months; and
- 2 Patient is being managed by a specialist spinal acute care and rehabilitation unit; and
- 3 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

Note: Indications marked with * are unapproved indications.

Renewal — (spinal cord injury*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period; and
- 2 The patient has not received more than two doses of zoledronic acid for this indication.

The patient must not have had more than 1 prior approval.

Notes: No further renewals will be subsidised. A maximum of 2 vials of zoledronic acid treatment for spinal cord injury will be subsidised. Indications marked with * are unapproved indications.

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA).

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.

- b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Hyperuricaemia and Antigout

ALLOPURINOL

* Tab 100 mg	11.47	500	✓ DP-Allopurinol
* Tab 300 mg	28.57	500	✓ DP-Allopurinol

BENZBROMARONE – Special Authority see [SA1963 below](#) – Retail pharmacy

Tab 50 mg	22.50	100	✓ Narcaricin mite ^{S29}
Tab 100 mg	13.50	30	✓ Desuric ^{S29}
	45.00	100	✓ Urinorm ^{S29}
			✓ Benzbromaron AL
			100 ^{S29}

➔SA1963 Special Authority for Subsidy

Renewal from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefitting from the treatment; and
- 2 There is no evidence of liver toxicity and patient is continuing to receive regular (at least every three months) liver function tests.

COLCHICINE

* Tab 500 mcg	6.00	100	✓ Colgout
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FEBUXOSTAT – Special Authority see [SA2054 below](#) – Retail pharmacy

Tab 80 mg	20.00	28	✓ Febuxostat multichem
Tab 120 mg	20.00	28	✓ Febuxostat multichem

➔SA2054 Special Authority for Subsidy

Initial application — (Gout) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

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

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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- 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
- 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
 - The patient has previously had an initial Special Authority approval for benzbromarone for treatment of gout.

Initial application — (Tumour lysis syndrome) only from a haematologist or oncologist. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- Patient is scheduled to receive cancer therapy carrying an intermediate or high risk of tumour lysis syndrome; and
- Patient has a documented history of allopurinol intolerance.

Renewal — (Gout) from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefitting from treatment.

Renewal — (Tumour lysis syndrome) only from a haematologist or oncologist. Approvals valid for 6 weeks where the treatment remains appropriate and the patient is benefitting from treatment.

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.

PROBENECID

* Tab 500 mg	66.95	100	✓ Probenecid-AFT
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Muscle Relaxants

BACLOFEN

* Tab 10 mg	4.20	100	✓ Pacifen
Inj 0.05 mg per ml, 1 ml ampoule – Subsidy by endorsement.....	11.55	1	✓ Lioresal Intrathecal
Subsidised only for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects and the prescription is endorsed accordingly.			
Inj 2 mg per ml, 5 ml ampoule – Subsidy by endorsement.....	306.82	5	✓ Medsurge
Subsidised only for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects and the prescription is endorsed accordingly.			

DANTROLENE

Cap 25 mg	97.50	100	✓ Dantrium
Cap 50 mg	77.00	100	✓ Dantrium S29 ^{S29}
			✓ Dantrium

ORPHENADRINE CITRATE

Tab 100 mg	20.76	100	✓ Norflex
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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

Agents for Parkinsonism and Related Disorders

Dopamine Agonists and Related Agents

AMANTADINE HYDROCHLORIDE

▲ Cap 100 mg 38.24 60 ✓ Symmetrel

APOMORPHINE HYDROCHLORIDE

▲ Inj 10 mg per ml, 2 ml ampoule 59.50 5 ✓ Movapo

▲ Inj 10 mg per ml, 5 ml ampoule 121.84 5 ✓ Movapo

ENTACAPONE

▲ Tab 200 mg 18.04 100 ✓ Comtan

LEVODOPA WITH BENSERAZIDE

* Tab dispersible 50 mg with benserazide 12.5 mg 13.25 100 ✓ Madopar Rapid

* Cap 50 mg with benserazide 12.5 mg 13.75 100 ✓ Madopar 62.5

* Cap 100 mg with benserazide 25 mg 15.80 100 ✓ Madopar 125

* Cap long-acting 100 mg with benserazide 25 mg 22.85 100 ✓ Madopar HBS

* Cap 200 mg with benserazide 50 mg 26.25 100 ✓ Madopar 250

LEVODOPA WITH CARBIDOPA

* Tab 100 mg with carbidopa 25 mg 21.11 100 ✓ Sinemet

* Tab long-acting 200 mg with carbidopa 50 mg 43.65 100 ✓ Sinemet CR

* Tab 250 mg with carbidopa 25 mg 38.39 100 ✓ Sinemet

PRAMIPEXOLE HYDROCHLORIDE

▲ Tab 0.25 mg 5.51 100 ✓ Ramipex

Ramipex to be Principal Supply on 1 December 2022

▲ Tab 1 mg 18.66 100 ✓ Ramipex

Ramipex to be Principal Supply on 1 December 2022

RASAGILINE

* Tab 1 mg 53.50 30 ✓ Azilect ^{\$29}

ROPINIROLE HYDROCHLORIDE

▲ Tab 0.25 mg 3.39 100 ✓ Mylan ^{\$29}

4.05 84 ✓ Ropin

▲ Tab 1 mg 4.70 100 ✓ Mylan ^{\$29}

4.95 84 ✓ Ropin

▲ Tab 2 mg 6.48 84 ✓ Ropin

▲ Tab 5 mg 14.50 84 ✓ Ropin

(Mylan ^{\$29} Tab 0.25 mg to be delisted 1 January 2023)

(Mylan ^{\$29} Tab 1 mg to be delisted 1 December 2022)

SELEGILINE HYDROCHLORIDE – Subsidy by endorsement

Subsidy by endorsement – Subsidised for patients who were taking selegiline hydrochloride prior to 1 August 2021 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of selegiline hydrochloride.

* Tab 5 mg 48.00 100 ✓ Eldepryl ^{\$29}

TOLCAPONE

▲ Tab 100 mg 152.38 100 ✓ Tasmar

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Anticholinergics				
BENZATROPINE MESYLATE				
Tab 2 mg	9.59	60	✓	Benztrop
Inj 1 mg per ml, 2 ml	95.00	5	✓	Phebra
a) Up to 10 inj available on a PSO				
b) Only on a PSO				
PROCYCLIDINE HYDROCHLORIDE				
Tab 5 mg	7.40	100	✓	Kemadrin

Agents for Essential Tremor, Chorea and Related Disorders

RILUZOLE – Special Authority see [SA1403 below](#) – Retail pharmacy

Wastage claimable

Tab 50 mg	130.00	56	✓	Rilutek
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»SA1403 Special Authority for Subsidy

Initial application only from a neurologist or respiratory specialist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has amyotrophic lateral sclerosis with disease duration of 5 years or less; and
- 2 The patient has at least 60 percent of predicted forced vital capacity within 2 months prior to the initial application; and
- 3 The patient has not undergone a tracheostomy; and
- 4 The patient has not experienced respiratory failure; and
- 5 Any of the following:
 - 5.1 The patient is ambulatory; or
 - 5.2 The patient is able to use upper limbs; or
 - 5.3 The patient is able to swallow.

Renewal from any relevant practitioner. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 The patient has not undergone a tracheostomy; and
- 2 The patient has not experienced respiratory failure; and
- 3 Any of the following:
 - 3.1 The patient is ambulatory; or
 - 3.2 The patient is able to use upper limbs; or
 - 3.3 The patient is able to swallow.

TETRABENAZINE				
Tab 25 mg	91.10	112	✓	Motetis

Anaesthetics

Local

LIDOCAINE [LIGNOCAINE]

Gel 2%, tube – Subsidy by endorsement	14.50	30 ml	✓	Xylocaine 2% Jelly
a) Up to 150 ml available on a PSO				
b) Subsidised only if prescribed for urethral or cervical administration and the prescription is endorsed accordingly.				
Gel 2%, 11 ml urethral syringe – Subsidy by endorsement.....	59.50	10	✓	Instillagel Lido
a) Up to 5 each available on a PSO				
b) Subsidised only if prescribed for urethral, cervical or rectal administration and the prescription is endorsed accordingly.				

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE				
Oral (gel) soln 2%.....	38.00	200 ml	✓	Mucosoothe
Inj 1%, 5 ml ampoule – Up to 25 inj available on a PSO.....	8.75	25	✓	Lidocaine-Baxter
	17.50	50		
	(35.00)			Xylocaine
Inj 2%, 5 ml ampoule – Up to 5 inj available on a PSO.....	8.25	25	✓	Lidocaine-Baxter
Inj 1%, 20 ml ampoule – Up to 5 inj available on a PSO.....	12.00	5		
	(20.00)			Xylocaine
Inj 1%, 20 ml vial – Up to 5 inj available on a PSO.....	6.20	5	✓	Lidocaine-Baxter
			✓	Lidocaine-Clarix
			✓	Lidocaine-Baxter
Inj 2%, 20 ml vial – Up to 5 inj available on a PSO.....	6.45	5		
LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDINE				
Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes –				
Subsidy by endorsement.....	103.32	10	✓	Pfizer
a) Up to 5 each available on a PSO				
b) Subsidised only if prescribed for urethral or cervical administration and the prescription is endorsed accordingly.				

Topical Local Anaesthetics

►SA0906 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years where the patient is a child with a chronic medical condition requiring frequent injections or venepuncture.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

LIDOCAINE [LIGNOCAINE] – Special Authority see [SA0906 above](#) – Retail pharmacy

Crm 4%.....	5.40	5 g OP	✓	LMX4
	27.00	30 g OP	✓	LMX4

LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE – Special Authority see [SA0906 above](#) – Retail pharmacy

Crm 2.5% with prilocaine 2.5%.....	45.00	30 g OP	✓	EMLA
Crm 2.5% with prilocaine 2.5% (5 g tubes)	45.00	5	✓	EMLA

Analgesics

For Anti-inflammatory NSAIDs refer to MUSCULOSKELETAL, [page 110](#)

Non-opioid Analgesics

ASPIRIN

* Tab dispersible 300 mg – Up to 30 tab available on a PSO.....4.50 100 ✓ **Ethics Aspirin**

CAPSAICIN – Subsidy by endorsement

Subsidised only if prescribed for post-herpetic neuralgia or diabetic peripheral neuropathy and the prescription is endorsed accordingly.

Crm 0.075%.....	11.95	45 g OP	✓	Zostrix HP
	15.83	57 g OP	✓	Rugby Capsaicin
				Topical
				Cream \$29

NEFOPAM HYDROCHLORIDE

Tab 30 mg23.40 90 ✓ **Acupan**

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PARACETAMOL				
Tab 500 mg - blister pack	19.75	1,000	✓	<u>Pacimol</u>
a) Maximum of 300 tab per prescription; can be waived by endorsement b) Up to 30 tab available on a PSO c) <ol style="list-style-type: none"> 1) Subsidy by endorsement for higher quantities is available for patients with long term conditions who require regular daily dosing for one month or greater, and the prescription is annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition. 2) Maximum of 100 tab per dispensing for non-endorsed patients. If quantities prescribed for more than 100 tabs (for non-endorsed patients), then dispense in repeat dispensings not exceeding 100 tab per dispensing. 				
Tab 500 mg - bottle pack – Maximum of 300 tab per prescription; can be waived by endorsement	17.92	1,000	✓	<u>Noumed Paracetamol</u>
1) Subsidy by endorsement for higher quantities is available for patients with long term conditions who require regular daily dosing for one month or greater, and the prescription is annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition. 2) Maximum of 100 tab per dispensing for non-endorsed patients. If quantities prescribed for more than 100 tabs (for non-endorsed patients), then dispense in repeat dispensings not exceeding 100 tab per dispensing.				
Oral liq 120 mg per 5 ml	5.45	1,000 ml	✓	<u>Paracare</u>
	10.50	200 ml OP	✓	<u>Avallon</u> <small>S29</small>
a) Maximum of 600 ml per prescription; can be waived by endorsement b) Up to 200 ml available on a PSO c) Not in combination d) <ol style="list-style-type: none"> 1) Maximum of 200 ml per dispensing for non-endorsed patients. If quantities prescribed exceed 200 ml (for non-endorsed patients), then dispense in repeat dispensing not exceeding 200 ml per dispensing. 2) Subsidy by endorsement for higher quantities is available for patients with long term conditions who require regular daily dosing for one month or greater and the prescription is endorsed or annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition. 				
Oral liq 240 mg per 5 ml	11.92	200 ml OP	✓	<u>Avallon</u> <small>S29</small>
a) Maximum of 600 ml per prescription; can be waived by endorsement b) Up to 200 ml available on a PSO c) Not in combination d) <ol style="list-style-type: none"> 1) Maximum of 200 ml per dispensing for non-endorsed patients. If quantities prescribed exceed 200 ml (for non-endorsed patients), then dispense in repeat dispensing not exceeding 200 ml per dispensing. 2) Subsidy by endorsement for higher quantities is available for patients with long term conditions who require regular daily dosing for one month or greater and the prescription is endorsed or annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition. 				
Oral liq 250 mg per 5 ml	6.25	1,000 ml	✓	<u>Paracare Double Strength</u>

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
a) Maximum of 600 ml per prescription; can be waived by endorsement				
b) Up to 100 ml available on a PSO				
c) Not in combination				
d)				
1) Maximum of 200 ml per dispensing for non-endorsed patients. If quantities prescribed exceed 200 ml (for non-endorsed patients), then dispense in repeat dispensing not exceeding 200 ml per dispensing.				
2) Subsidy by endorsement for higher quantities is available for patients with long term conditions who require regular daily dosing for one month or greater and the prescription is endorsed or annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition.				
* Suppos 125 mg	3.59	10	✓	Gacet
* Suppos 250 mg	4.18	10	✓	Gacet
* Suppos 500 mg	12.40	50	✓	Gacet

Opioid Analgesics

CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency

Tab 15 mg	6.25	100	✓	PSM
Tab 30 mg	7.45	100	✓	PSM
	32.80		✓	Aspen \$29
Tab 60 mg	14.25	100	✓	PSM

DIHYDROCODEINE TARTRATE

Tab long-acting 60 mg.....	8.60	60	✓	DHC Continus
DHC Continus to be Principal Supply on 1 December 2022				

FENTANYL

a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Inj 50 mcg per ml, 2 ml ampoule	3.75	10	✓	Boucher and Muir
Inj 50 mcg per ml, 10 ml ampoule	9.41	10	✓	Boucher and Muir
Patch 12.5 mcg per hour	6.99	5	✓	Fentanyl Sandoz
Patch 25 mcg per hour	7.99	5	✓	Fentanyl Sandoz
Patch 50 mcg per hour	9.49	5	✓	Fentanyl Sandoz
Patch 75 mcg per hour	17.99	5	✓	Fentanyl Sandoz
Patch 100 mcg per hour	18.59	5	✓	Fentanyl Sandoz

METHADONE HYDROCHLORIDE

a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
d) Extemporaneously compounded methadone will only be reimbursed at the rate of the cheapest form available (methadone powder, not methadone tablets).				
e) For methadone hydrochloride oral liquid refer Standard Formulae, page 246				
Tab 5 mg	1.40	10	✓	Methatabs
	1.45		✓	Methadone BNM
Oral liq 2 mg per ml	6.40	200 ml	✓	Biodone
Oral liq 5 mg per ml	6.40	200 ml	✓	Biodone Forte
Oral liq 10 mg per ml	7.50	200 ml	✓	Biodone Extra Forte
Inj 10 mg per ml, 1 ml	61.00	10	✓	AFT

(Methatabs Tab 5 mg to be delisted 1 February 2023)

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
MORPHINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Oral liq 1 mg per ml	11.98	200 ml	✓	RA-Morph
Oral liq 2 mg per ml	16.24	200 ml	✓	RA-Morph
Oral liq 5 mg per ml	19.44	200 ml	✓	Ordine ^{§29}
			✓	RA-Morph
Oral liq 10 mg per ml	27.74	200 ml	✓	Ordine ^{§29}
			✓	RA-Morph
MORPHINE SULPHATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab immediate-release 10 mg	2.80	10	✓	Sevredol
Tab immediate-release 20 mg	5.52	10	✓	Sevredol
Cap long-acting 10 mg	2.05	10	✓	m-Eslon
Cap long-acting 30 mg	3.00	10	✓	m-Eslon
Cap long-acting 60 mg	6.12	10	✓	m-Eslon
Cap long-acting 100 mg	7.13	10	✓	m-Eslon
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	6.99	5	✓	DBL Morphine Sulphate
Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	5.61	5	✓	DBL Morphine Sulphate
Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	7.08	5	✓	DBL Morphine Sulphate
Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	7.28	5	✓	DBL Morphine Sulphate
OXYCODONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab controlled-release 5 mg	2.69	20	✓	Oxycodone Sandoz
Tab controlled-release 10 mg	2.69	20	✓	Oxycodone Sandoz
Tab controlled-release 20 mg	3.49	20	✓	Oxycodone Sandoz
Tab controlled-release 40 mg	5.49	20	✓	Oxycodone Sandoz
Tab controlled-release 80 mg	12.99	20	✓	Oxycodone Sandoz
Cap immediate-release 5 mg	1.88	20	✓	OxyNorm
Cap immediate-release 10 mg	3.32	20	✓	OxyNorm
Cap immediate-release 20 mg	5.23	20	✓	OxyNorm
Oral liq 5 mg per 5 ml	11.20	250 ml	✓	OxyNorm
Inj 10 mg per ml, 1 ml ampoule	5.82	5	✓	Hameln
Inj 10 mg per ml, 2 ml ampoule	11.49	5	✓	Hameln
Inj 50 mg per ml, 1 ml ampoule	22.92	5	✓	Hameln
PARACETAMOL WITH CODEINE – Safety medicine; prescriber may determine dispensing frequency				
* Tab paracetamol 500 mg with codeine phosphate 8 mg	27.50	1,000	✓	Paracetamol + Codeine (Relieve)

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PETHIDINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab 50 mg	4.70	10	✓ PSM	
Inj 50 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	29.88	5	✓ DBL Pethidine Hydrochloride	
Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	30.72	5	✓ DBL Pethidine Hydrochloride	
TRAMADOL HYDROCHLORIDE				
Tab sustained-release 100 mg	1.52	20	✓ Tramal SR 100	
Tab sustained-release 150 mg	2.10	20	✓ Tramal SR 150	
Tab sustained-release 200 mg	2.75	20	✓ Tramal SR 200	
Cap 50 mg	2.80	100	✓ Arrow-Tramadol	

Antidepressants

Cyclic and Related Agents

AMITRIPTYLINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	2.49	100	✓ Arrow-Amitriptyline	
Tab 25 mg	1.51	100	✓ Arrow-Amitriptyline	
Tab 50 mg	2.51	100	✓ Arrow-Amitriptyline	
CLOMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	10.17	30	✓ Clomipramine Teva	
Tab 25 mg	11.99	30	✓ Clomipramine Teva	
DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE – Subsidy by endorsement				
a) Safety medicine; prescriber may determine dispensing frequency				
b) Subsidy by endorsement – Subsidised for patients who were taking dosulepin [dothiepin] hydrochloride prior to 1 June 2019 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of dosulepin [dothiepin] hydrochloride.				
Tab 75 mg	3.85	30	✓ Dosulepin Mylan	
Cap 25 mg	7.83	50	✓ Dosulepin Mylan ^{S29}	
IMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	5.48	50	✓ Tofranil	
Tab 25 mg	10.96	100	✓ Tofranil	
Tab 25 mg	8.80	50	✓ Tofranil	
NORTRIPTYLINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	2.44	100	✓ Norpress	
Tab 25 mg	5.98	180	✓ Norpress	

Monoamine-Oxidase Inhibitors (MAOIs) - Non Selective

TRANLYCYPROMINE SULPHATE				
Tab 10 mg	12.85	28	✓ Parnate ^{S29} ^{S29}	
	22.94	50	✓ Parnate	
	45.88	100	✓ Parnate ^{S29} ^{S29}	
	96.00		✓ Parnate ^{S29} ^{S29}	

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Monoamine-Oxidase Type A Inhibitors

MOCLOBEMIDE

* Tab 150 mg	11.80	60	✓ Aurorix
* Tab 300 mg	19.25	60	✓ Aurorix

Selective Serotonin Reuptake Inhibitors

CITALOPRAM HYDROBROMIDE

* Tab 20 mg	1.91	84	✓ PSM Citalopram
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ESCITALOPRAM

* Tab 10 mg	1.07	28	✓ Escitalopram (Ethics)
* Tab 20 mg	1.92	28	✓ Escitalopram (Ethics)

FLUOXETINE HYDROCHLORIDE

* Tab dispersible 20 mg, scored – Subsidy by endorsement	2.50	28	✓ Fluox
Subsidised by endorsement			
1) When prescribed for a patient who cannot swallow whole tablets or capsules and the prescription is endorsed accordingly; or			
2) When prescribed in a daily dose that is not a multiple of 20 mg in which case the prescription is deemed to be endorsed. Note: Tablets should be combined with capsules to facilitate incremental 10 mg doses.			

Cap 20 mg	2.91	84	✓ Fluox
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PAROXETINE

* Tab 20 mg	4.11	90	✓ Loxamine
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SERTRALINE

* Tab 50 mg	0.92	30	✓ Setrona
* Tab 100 mg	1.61	30	✓ Setrona AU
			✓ Setrona
			✓ Setrona AU

Other Antidepressants

MIRTAZAPINE

Tab 30 mg	2.60	28	✓ Noumed
Tab 45 mg	3.45	28	✓ Noumed

VENLAFAXINE

* Cap 37.5 mg	6.38	84	✓ Enlafax XR
* Cap 75 mg	8.11	84	✓ Enlafax XR
* Cap 150 mg	11.16	84	✓ Enlafax XR

Antiepilepsy Drugs

Agents for Control of Status Epilepticus

DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency

Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement	23.66	5	✓ Hospira
a) Up to 5 inj available on a PSO			
b) Only on a PSO			
c) PSO must be endorsed “not for anaesthetic procedures”.			
Rectal tubes 5 mg – Up to 5 tube available on a PSO	54.58	5	✓ Stesolid

▲ Three months supply may be dispensed at one time if endorsed “certified exemption” by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PHENYTOIN SODIUM				
* Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	104.58	5	✓	Hospira
* Inj 50 mg per ml, 5 ml ampoule – Up to 5 inj available on a PSO	154.01	5	✓	Hospira

Control of Epilepsy

CARBAMAZEPINE				
* Tab 200 mg	14.53	100	✓	Tegretol
* Tab long-acting 200 mg	16.98	100	✓	Tegretol CR
* Tab 400 mg	34.58	100	✓	Tegretol
* Tab long-acting 400 mg	39.17	100	✓	Tegretol CR
* Oral liq 20 mg per ml	26.37	250 ml	✓	Tegretol
CLOBAZAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	9.12	50	✓	Frisium
CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Oral drops 2.5 mg per ml	7.38	10 ml OP	✓	Rivotril
ETHOSUXIMIDE				
Cap 250 mg	78.89	56	✓	Essential Ethosuximide ^{S29}
	140.88	100	✓	Zarontin
Oral liq 250 mg per 5 ml	56.35	200 ml	✓	Zarontin
GABAPENTIN				
Note: Not subsidised in combination with subsidised pregabalin				
* Cap 100 mg	6.45	100	✓	Nupentin
* Cap 300 mg	8.45	100	✓	Nupentin
* Cap 400 mg	10.26	100	✓	Nupentin
LACOSAMIDE – Special Authority see SA1125 below – Retail pharmacy				
▲ Tab 50 mg	25.04	14	✓	Vimpat
▲ Tab 100 mg	50.06	14	✓	Vimpat
	200.24	56	✓	Vimpat
▲ Tab 150 mg	75.10	14	✓	Vimpat
	300.40	56	✓	Vimpat
▲ Tab 200 mg	400.55	56	✓	Vimpat

➡ [SA1125](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:
Both:

- 1 Patient has partial-onset epilepsy; and
- 2 Seizures are not adequately controlled by, or patient has experienced unacceptable side effects from, optimal treatment with all of the following: sodium valproate, topiramate, levetiracetam and any two of carbamazepine, lamotrigine and phenytoin sodium (see Note).

Note: "Optimal treatment" is defined as treatment which is 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. Women of childbearing age are not required to have a trial of sodium valproate.

Renewal from any relevant practitioner. Approvals valid for 24 months where the patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life compared with that prior to starting lacosamide treatment (see Note).

Note: 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LAMOTRIGINE				
▲ Tab dispersible 2 mg	55.00	30	✓	Lamictal
▲ Tab dispersible 5 mg	50.00	30	✓	Lamictal
* Tab dispersible 25 mg	2.76	56	✓	Logem
* Tab dispersible 50 mg	3.31	56	✓	Logem
* Tab dispersible 100 mg	4.40	56	✓	Logem
LEVETIRACETAM				
Tab 250 mg	4.99	60	✓	Everet
Tab 500 mg	8.79	60	✓	Everet
Tab 750 mg	14.39	60	✓	Everet
Tab 1,000 mg	18.59	60	✓	Everet
Oral liq 100 mg per ml	44.78	300 ml OP	✓	Levetiracetam-AFT
PHENOBARBITONE				
For phenobarbitone oral liquid refer Standard Formulae, page 246				
* Tab 15 mg	40.00	500	✓	PSM
* Tab 30 mg	40.00	500	✓	PSM
PHENYTOIN SODIUM				
* Tab 50 mg	75.00	200	✓	Dilantin Infatab
Cap 30 mg	74.00	200	✓	Dilantin
Cap 100 mg	37.00	200	✓	Dilantin
* Oral liq 30 mg per 5 ml	22.03	500 ml	✓	Dilantin
PREGABALIN				
Note: Not subsidised in combination with subsidised gabapentin				
Cap 25 mg	2.25	56	✓	Pregabalin Pfizer
* Cap 75 mg	2.65	56	✓	Pregabalin Pfizer
Cap 150 mg	4.01	56	✓	Lyrica
			✓	Pregabalin Pfizer
Cap 300 mg	7.38	56	✓	Pregabalin Pfizer
PRIMIDONE				
* Tab 250 mg	37.35	100	✓	Apo-Primidone
			✓	Primidone Clinect
<i>(Apo-Primidone Tab 250 mg to be delisted 1 January 2023)</i>				
SODIUM VALPROATE				
Tab 100 mg	13.65	100	✓	Epilim Crushable
Tab 200 mg EC	27.44	100	✓	Epilim
Tab 500 mg EC	52.24	100	✓	Epilim
* Oral liq 200 mg per 5 ml	20.48	300 ml	✓	Epilim S/F Liquid
			✓	Epilim Syrup
* Inj 100 mg per ml, 4 ml	41.50	1	✓	Epilim IV
STIRIPENTOL – Special Authority see SA1330 below – Retail pharmacy				
Cap 250 mg	509.29	60	✓	Diacomit ^{S29}
Powder for oral liq 250 mg sachet	509.29	60	✓	Diacomit ^{S29}

► **SA1330** Special Authority for Subsidy

Initial application only from a paediatric neurologist or Practitioner on the recommendation of a paediatric neurologist.

Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has confirmed diagnosis of Dravet syndrome; and

continued...

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 2 Seizures have been inadequately controlled by appropriate courses of sodium valproate, clobazam and at least two of the following: topiramate, levetiracetam, ketogenic diet.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where the patient continues to benefit from treatment as measured by reduced seizure frequency from baseline.

TOPIRAMATE

▲ Tab 25 mg	11.07	60	✓	Arrow-Topiramate
			✓	Topiramate Actavis
	26.04		✓	Topamax
▲ Tab 50 mg	18.81	60	✓	Arrow-Topiramate
			✓	Topiramate Actavis
	44.26		✓	Topamax
▲ Tab 100 mg	31.99	60	✓	Arrow-Topiramate
			✓	Topiramate Actavis
	75.25		✓	Topamax
▲ Tab 200 mg	55.19	60	✓	Arrow-Topiramate
			✓	Topiramate Actavis
	129.85		✓	Topamax
▲ Sprinkle cap 15 mg	20.84	60	✓	Topamax
▲ Sprinkle cap 25 mg	26.04	60	✓	Topamax

VIGABATRIN – Special Authority see [SA2088 below](#) – Retail pharmacy

▲ Tab 500 mg	119.30	100	✓	Sabril
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➔SA2088 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 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; or
 - 1.3 Patient has tuberous sclerosis complex; 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) 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.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and
- 2 Either:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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continued...

- 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) to monitor the patient's visual fields..

Notes: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

Antimigraine Preparations

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, [page 110](#)

Acute Migraine Treatment

RIZATRIPTAN

Tab orodispersible 10 mg	3.65	30	✓ Rizamelt
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SUMATRIPTAN

Tab 50 mg	14.41	90	✓ Sumagran
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Tab 100 mg	22.68	90	✓ Sumagran
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Inj 12 mg per ml, 0.5 ml prefilled pen – Maximum of 10 inj per prescription	34.00	2 OP	✓ Imigran
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Prophylaxis of Migraine

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, [page 50](#)

PIZOTIFEN

* Tab 500 mcg	23.21	100	✓ Sandomigran
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Antinausea and Vertigo Agents

For Antispasmodics refer to ALIMENTARY TRACT, [page 8](#)

APREPITANT – Special Authority see [SA0987 below](#) – Retail pharmacy

Cap 2 x 80 mg and 1 x 125 mg	30.00	3 OP	✓ Emend Tri-Pack
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►SA0987 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.

Renewal from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.

BETAHISTINE DIHYDROCHLORIDE

* Tab 16 mg	4.62	100	✓ Serc
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CYCLIZINE HYDROCHLORIDE

Tab 50 mg	0.49	10	✓ Nausicalm
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CYCLIZINE LACTATE

Inj 50 mg per ml, 1 ml ampoule	16.36	10	✓ Hameln
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Hameln to be Principal Supply on 1 December 2022

DOMPERIDONE

* Tab 10 mg	2.85	100	✓ Pharmacy Health
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NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
HYOSCINE HYDROBROMIDE				
* Inj 400 mcg per ml, 1 ml ampoule	93.00	10	✓	Martindale <small>S29</small>
Patch 1.5 mg – Special Authority see SA1998 below – Retail pharmacy.....	14.11	2	✓	Scopoderm TTS
►SA1998 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria: Either:				
1 Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease where the patient cannot tolerate or does not adequately respond to oral anti-nausea agents; or				
2 Control of clozapine-induced hypersalivation where trials of at least two other alternative treatments have proven ineffective.				
Renewal from any relevant practitioner. Approvals valid for 1 year where the treatment remains appropriate and the patient is benefiting from treatment.				
METOCLOPRAMIDE HYDROCHLORIDE				
* Tab 10 mg – Up to 30 tab available on a PSO	1.30	100	✓	Metoclopramide Actavis 10
* Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	7.00	10	✓	Baxter
	9.50		✓	Pfizer
Baxter to be Principal Supply on 1 December 2022 (Pfizer Inj 5 mg per ml, 2 ml ampoule to be delisted 1 December 2022)				
ONDANSETRON				
* Tab 4 mg	2.68	50	✓	Onrex
* Tab disp 4 mg – Up to 10 tab available on a PSO	0.76	10	✓	Ondansetron ODT-DRLA
* Tab 8 mg	4.57	50	✓	Onrex
* Tab disp 8 mg – Up to 10 tab available on a PSO	1.13	10	✓	Ondansetron ODT-DRLA
PROCHLORPERAZINE				
* Tab 3 mg buccal.....	5.97 (30.00)	50		Buccastem
* Tab 5 mg – Up to 30 tab available on a PSO	8.00	250	✓	Nausafix
* Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO	25.81	10	✓	Stemetil

Antipsychotics

General

AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 100 mg	5.15	30	✓	Sulprix
Tab 200 mg	14.96	60	✓	Sulprix
Tab 400 mg	29.78	60	✓	Sulprix
ARIPRAZOLE – Safety medicine; prescriber may determine dispensing frequency				
Tab 5 mg	10.50	30	✓	Aripiprazole Sandoz
Tab 10 mg	10.50	30	✓	Aripiprazole Sandoz
Tab 15 mg	10.50	30	✓	Aripiprazole Sandoz
Tab 20 mg	10.50	30	✓	Aripiprazole Sandoz
Tab 30 mg	10.50	30	✓	Aripiprazole Sandoz

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency			
Tab 10 mg – Up to 30 tab available on a PSO	14.83	100	✓ Largactil
Tab 25 mg – Up to 30 tab available on a PSO	15.62	100	✓ Largactil
Tab 100 mg – Up to 30 tab available on a PSO	36.73	100	✓ Largactil
Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO	30.79	10	✓ Largactil
CLOZAPINE – Hospital pharmacy [HP4]			
Safety medicine; prescriber may determine dispensing frequency			
Tab 25 mg	6.69	50	✓ Clopine
	13.37	100	✓ Clozaril
			✓ Clopine
			✓ Clozaril
Tab 50 mg	8.67	50	✓ Clopine
	17.33	100	✓ Clopine
Tab 100 mg	17.33	50	✓ Clopine
			✓ Clozaril
	34.65	100	✓ Clopine
			✓ Clozaril
Tab 200 mg	34.65	50	✓ Clopine
	69.30	100	✓ Clopine
Suspension 50 mg per ml	67.62	100 ml	✓ Versacloz
HALOPERIDOL – Safety medicine; prescriber may determine dispensing frequency			
Tab 500 mcg – Up to 30 tab available on a PSO	6.23	100	✓ Serenace
Tab 1.5 mg – Up to 30 tab available on a PSO	9.43	100	✓ Serenace
Tab 5 mg – Up to 30 tab available on a PSO	14.86	50	✓ Serenace
	29.72	100	✓ Serenace
Oral liq 2 mg per ml – Up to 200 ml available on a PSO	23.84	100 ml	✓ Serenace
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	21.55	10	✓ Serenace
LEVOMEPROMAZINE – Safety medicine; prescriber may determine dispensing frequency			
Tab 25 mg (33.8 mg as a maleate)	16.10	100	✓ Nozinan (Swiss)
Tab 25 mg as a maleate	16.10	100	✓ Nozinan
Tab 100 mg (135 mg as a maleate)	41.75	100	✓ Nozinan (Swiss)
Tab 100 mg as a maleate	41.75	100	✓ Nozinan
LEVOMEPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency			
Inj 25 mg per ml, 1 ml ampoule	16.75	5	✓ Neuraxpharm ^{S29}
	33.50	10	✓ Nozinan S29 ^{S29}
			✓ Nozinan
LITHIUM CARBONATE – Safety medicine; prescriber may determine dispensing frequency			
Tab long-acting 400 mg	72.00	100	✓ Priadel
Cap 250 mg	9.42	100	✓ Douglas
OLANZAPINE – Safety medicine; prescriber may determine dispensing frequency			
Tab 2.5 mg	1.35	28	✓ Zypine
Tab 5 mg	1.58	28	✓ Zypine
Tab orodispersible 5 mg	1.81	28	✓ Zypine ODT
Tab 10 mg	2.01	28	✓ Zypine
Tab orodispersible 10 mg	2.38	28	✓ Zypine ODT
PERICYAZINE – Safety medicine; prescriber may determine dispensing frequency			
Tab 2.5 mg	10.49	84	✓ Neulactil
	12.49	100	✓ Neulactil
Tab 10 mg	37.34	84	✓ Neulactil
	44.45	100	✓ Neulactil

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	2.15	90	✓	Quetapel
Tab 100 mg	5.06	90	✓	Quetapel
Tab 200 mg	8.90	90	✓	Quetapel
Tab 300 mg	12.86	90	✓	Quetapel
RISPERIDONE – Safety medicine; prescriber may determine dispensing frequency				
Tab 0.5 mg	1.86	60	✓	Risperidone (Teva)
Tab 1 mg	2.06	60	✓	Risperidone (Teva)
Tab 2 mg	2.29	60	✓	Risperidone (Teva)
Tab 3 mg	2.50	60	✓	Risperidone (Teva)
Tab 4 mg	3.42	60	✓	Risperidone (Teva)
Oral liq 1 mg per ml	8.90	30 ml	✓	Risperon
ZIPRASIDONE – Safety medicine; prescriber may determine dispensing frequency				
Cap 20 mg	17.90	60	✓	Zusdone
Cap 40 mg	27.41	60	✓	Zusdone
Cap 60 mg	38.39	60	✓	Zusdone
Cap 80 mg	46.55	60	✓	Zusdone
ZUCLOPENTHIXOL HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	31.45	100	✓	Clopixol

Depot Injections

FLUPENTHIXOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency				
Inj 20 mg per ml, 1 ml – Up to 5 inj available on a PSO	13.14	5	✓	Fluanxol
Inj 20 mg per ml, 2 ml – Up to 5 inj available on a PSO	20.90	5	✓	Fluanxol
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	40.87	5	✓	Fluanxol
HALOPERIDOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency				
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	28.39	5	✓	Haldol
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	55.90	5	✓	Haldol Concentrate
			✓	Haldol
				Decanoas <small>S29</small>
OLANZAPINE – Special Authority see SA1428 below – Retail pharmacy				
Safety medicine; prescriber may determine dispensing frequency				
Inj 210 mg vial	252.00	1	✓	Zyprexa Relprevv
Inj 300 mg vial	414.00	1	✓	Zyprexa Relprevv
Inj 405 mg vial	504.00	1	✓	Zyprexa Relprevv

►SA1428 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Either:

- 1 The patient has had an initial Special Authority approval for paliperidone depot injection or risperidone depot injection; or
- 2 All of the following:
 - 2.1 The patient has schizophrenia; and
 - 2.2 The patient has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
 - 2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

Renewal from any relevant practitioner. Approvals valid for 12 months where the initiation of olanzapine depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

Note: The patient should be monitored for post-injection syndrome for at least two hours after each injection.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PALIPERIDONE – Special Authority see SA1429 below – Retail pharmacy				
Safety medicine; prescriber may determine dispensing frequency				
Inj 25 mg syringe	194.25	1	✓	Invega Sustenna
Inj 50 mg syringe	271.95	1	✓	Invega Sustenna
Inj 75 mg syringe	357.42	1	✓	Invega Sustenna
Inj 100 mg syringe	435.12	1	✓	Invega Sustenna
Inj 150 mg syringe	435.12	1	✓	Invega Sustenna

➤ **SA1429** **Special Authority for Subsidy**

Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Either:

- 1 The patient has had an initial Special Authority approval for risperidone depot injection or olanzapine depot injection; or
- 2 All of the following:
 - 2.1 The patient has schizophrenia or other psychotic disorder; and
 - 2.2 Has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
 - 2.3 Has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.

Renewal from any relevant practitioner. Approvals valid for 12 months where the initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

Note: Paliperidone depot injection should ideally be used as monotherapy (i.e. without concurrent use of any other antipsychotic medication). In some cases, it may be clinically appropriate to attempt to treat a patient with typical antipsychotic agents in depot injectable form before trialling paliperidone depot injection.

RISPERIDONE – Special Authority see [SA1427 below](#) – Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency				
Inj 25 mg vial	135.98	1	✓	Risperdal Consta
Inj 37.5 mg vial	178.71	1	✓	Risperdal Consta
Inj 50 mg vial	217.56	1	✓	Risperdal Consta

➤ **SA1427** **Special Authority for Subsidy**

Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Either:

- 1 The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection; or
- 2 All of the following:
 - 2.1 The patient has schizophrenia or other psychotic disorder; and
 - 2.2 Has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
 - 2.3 Has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.

Renewal from any relevant practitioner. Approvals valid for 12 months where the initiation of risperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

Note: Risperidone depot injection should ideally be used as monotherapy (i.e. without concurrent use of any other antipsychotic medication). In some cases, it may be clinically appropriate to attempt to treat a patient with typical antipsychotic agents in depot injectable form before trialling risperidone depot injection.

ZUCLOPENTHIXOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency

Inj 200 mg per ml, 1 ml – Up to 5 inj available on a PSO	19.80	5	✓	Clopixol
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Anxiolytics

BUSPIRONE HYDROCHLORIDE

* Tab 5 mg	18.50	100	✓	Buspirone Viatris
* Tab 10 mg	12.50	100	✓	Buspirone Viatris

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 500 mcg.....	5.64	100	✓	Paxam
Tab 2 mg	10.78	100	✓	Paxam
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 2 mg	61.07	500	✓	Arrow-Diazepam
Tab 5 mg	73.60	500	✓	Arrow-Diazepam
LORAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 1 mg	9.72	250	✓	Ativan
Tab 2.5 mg	12.50	100	✓	Ativan

Multiple Sclerosis Treatments

►SA2140 Special Authority for Subsidy

Initial application — (Multiple sclerosis) only from a neurologist or general physician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been confirmed by a neurologist; and
- 2 Patients has an EDSS score between 0 – 6.0; and
- 3 Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months; and
- 4 All of the following:
 - 4.1 Each significant attack must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic); and
 - 4.2 Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
 - 4.3 Each significant attack has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant); and
 - 4.4 Each significant attack can be distinguished from the effects of general fatigue; and is not associated with a fever ($T > 37.5^{\circ}\text{C}$); and
 - 4.5 Either:
 - 4.5.1 Each significant attack is severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point; or
 - 4.5.2 Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and
- 5 Evidence of new inflammatory activity on an MRI scan within the past 24 months; and
- 6 Any of the following:
 - 6.1 A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion; or
 - 6.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or
 - 6.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or
 - 6.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack that occurred within the last 2 years; or
 - 6.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan.

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

continued...

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
continued...			
Renewal — (Multiple sclerosis) only from a neurologist or general physician. Approvals valid for 12 months where patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use of unilateral or bilateral aids at any time in the last six months (i.e. the patient has walked 100 metres or more with or without aids in the last six months). Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier. Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
DIMETHYL FUMARATE — Special Authority see SA2140 on the previous page — Retail pharmacy			
a) Wastage claimable			
b) Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
Cap 120 mg	520.00	14	✓ Tecfidera
Cap 240 mg	2,000.00	56	✓ Tecfidera
FINGOLIMOD — Special Authority see SA2140 on the previous page — Retail pharmacy			
a) Wastage claimable			
b) Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
Cap 0.5 mg	2,200.00	28	✓ Gilenya
GLATIRAMER ACETATE — Special Authority see SA2140 on the previous page — Retail pharmacy			
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
Inj 40 mg prefilled syringe	1,137.48	12	✓ Copaxone
INTERFERON BETA-1-ALPHA — Special Authority see SA2140 on the previous page — Retail pharmacy			
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
Inj 6 million iu prefilled syringe	1,170.00	4	✓ Avonex
Injection 6 million iu per 0.5 ml pen injector	1,170.00	4	✓ Avonex Pen
INTERFERON BETA-1-BETA — Special Authority see SA2140 on the previous page — Retail pharmacy			
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
Inj 8 million iu per 1 ml	1,322.89	15	✓ Betaferon
NATALIZUMAB — Special Authority see SA2140 on the previous page — Retail pharmacy			
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
Inj 20 mg per ml, 15 ml vial	1,750.00	1	✓ Tysabri
OCRELIZUMAB — Special Authority see SA2140 on the previous page — Retail pharmacy			
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
Inj 30 mg per ml, 10 ml vial	9,346.00	1	✓ Ocrevus
TERIFLUNOMIDE — Special Authority see SA2140 on the previous page — Retail pharmacy			
a) Wastage claimable			
b) Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.			
Tab 14 mg	659.90	28	✓ Aubagio

Sedatives and Hypnotics

MELATONIN — Special Authority see SA1666 below — Retail pharmacy			
Tab modified-release 2 mg — No more than 5 tab per day	11.50	30	✓ Vigisom

► [SA1666](#) Special Authority for Subsidy

Initial application only from a psychiatrist, paediatrician, neurologist, respiratory specialist or medical practitioner on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with persistent and distressing insomnia secondary to a neurodevelopmental disorder

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- (including, but not limited to, autism spectrum disorder or attention deficit hyperactivity disorder)*; and
- 2 Behavioural and environmental approaches have been tried and were unsuccessful, or are inappropriate; and
- 3 Funded modified-release melatonin is to be given at doses no greater than 10 mg per day; and
- 4 Patient is aged 18 years or under*.

Renewal only from a psychiatrist, paediatrician, neurologist, respiratory specialist or medical practitioner on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient is aged 18 years or under*; and
- 2 Patient has demonstrated clinically meaningful benefit from funded modified-release melatonin (clinician determined); and
- 3 Patient has had a trial of funded modified-release melatonin discontinuation within the past 12 months and has had a recurrence of persistent and distressing insomnia; and
- 4 Funded modified-release melatonin is to be given at doses no greater than 10 mg per day.

Note: Indications marked with * are unapproved indications.

MIDAZOLAM – Safety medicine; prescriber may determine dispensing frequency

Inj 1 mg per ml, 5 ml ampoule	5.50	10	✓	Midazolam-Baxter
Inj 1 mg per ml, 5 ml plastic ampoule – Up to 10 inj available on a PSO	17.28	10	✓	Pfizer
On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only.				
Inj 5 mg per ml, 3 ml ampoule	4.50	5	✓	Midazolam-Baxter
Inj 5 mg per ml, 3 ml plastic ampoule – Up to 5 inj available on a PSO	13.09	5	✓	Pfizer
On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only.				

PHENOBARBITONE SODIUM – Special Authority see [SA1386 below](#) – Retail pharmacy

Inj 200 mg per ml, 1 ml ampoule	103.30	10	✓	Max Health <small>§29</small>
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► [SA1386](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 For the treatment of terminal agitation that is unresponsive to other agents; and
- 2 The applicant is part of a multidisciplinary team working in palliative care.

TEMAZEPAM – Safety medicine; prescriber may determine dispensing frequency

Tab 10 mg	1.33	25	✓	Normison
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TRIAZOLAM – Safety medicine; prescriber may determine dispensing frequency

Tab 125 mcg	5.10	100		
	(9.85)			Hypam
Tab 250 mcg	4.10	100		
	(11.20)			Hypam

ZOPICLONE – Safety medicine; prescriber may determine dispensing frequency

Tab 7.5 mg	10.80	500	✓	Zopiclone Actavis
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Stimulants/ADHD Treatments				
ATOMOXETINE				
Cap 10 mg	18.41	28	✓	APO-Atomoxetine
			✓	APO-Atomoxetine
				S29 S29
			✓	Generic Partners
	107.03		✓	Strattera
Cap 18 mg	27.06	28	✓	APO-Atomoxetine
			✓	Generic Partners
	107.03		✓	Strattera
Cap 25 mg	29.22	28	✓	APO-Atomoxetine
			✓	Generic Partners
Cap 40 mg	29.22	28	✓	APO-Atomoxetine
			✓	Generic Partners
	107.03		✓	Strattera
Cap 60 mg	46.51	28	✓	APO-Atomoxetine
			✓	APO-Atomoxetine
				S29 S29
			✓	Generic Partners
Cap 80 mg	56.45	28	✓	APO-Atomoxetine
			✓	APO-Atomoxetine
				S29 S29
			✓	Generic Partners
Cap 100 mg	58.48	28	✓	APO-Atomoxetine
			✓	APO-Atomoxetine
				S29 S29
			✓	Generic Partners
DEXAMFETAMINE SULFATE – Special Authority see SA1149 below – Retail pharmacy				
a) Brand switch fee payable (Pharmacode 2641356) - see page 244 for details				
b) Only on a controlled drug form				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab 5 mg	21.00	100	✓	PSM
	28.50		✓	Aspen S29

► **SA1149** Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) patients aged 5 years or over; and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either:

- 3.1 Applicant is a paediatrician or psychiatrist; or
- 3.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

Initial application — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

continued...

▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

Both:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) patients under 5 years of age; and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria.

Initial application — (Narcolepsy) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.

Renewal — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
 - 2.1 Applicant is a paediatrician or psychiatrist; or
 - 2.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

Renewal — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (Narcolepsy) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.

METHYLPHENIDATE HYDROCHLORIDE – Special Authority see [SA1964 below](#) – Retail pharmacy

a) Only on a controlled drug form			
b) Safety medicine; prescriber may determine dispensing frequency			
Tab immediate-release 5 mg.....	3.20	30	✓ Rubifen
Tab immediate-release 10 mg.....	3.00	30	✓ Ritalin
			✓ Rubifen
Tab extended-release 18 mg.....	7.75	30	✓ Methylphenidate ER - Teva
Tab immediate-release 20 mg.....	7.85	30	✓ Rubifen
Tab sustained-release 20 mg.....	10.95	30	✓ Rubifen SR
Tab extended-release 27 mg.....	11.45	30	✓ Methylphenidate ER - Teva
Tab extended-release 36 mg.....	15.50	30	✓ Methylphenidate ER - Teva
Tab extended-release 54 mg.....	22.25	30	✓ Methylphenidate ER - Teva

► [SA1964](#) Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) patients aged 5 years or over; and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either:
 - 3.1 Applicant is a paediatrician or psychiatrist; or
 - 3.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

Initial application — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) patients under 5 years of age; and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria.

Initial application — (Narcolepsy*) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.

Note: *narcolepsy is not a registered indication for Methylphenidate ER – Teva.

Renewal — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
 - 2.1 Applicant is a paediatrician or psychiatrist; or
 - 2.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

Renewal — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (Narcolepsy*) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.

Note: *narcolepsy is not a registered indication for Methylphenidate ER – Teva.

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE – Special Authority see [SA1965 below](#) – Retail pharmacy

a) Only on a controlled drug form		
b) Safety medicine; prescriber may determine dispensing frequency		
Tab extended-release 18 mg.....	30	✓ Concerta
Tab extended-release 27 mg.....	30	✓ Concerta
Tab extended-release 36 mg.....	30	✓ Concerta
Tab extended-release 54 mg.....	30	✓ Concerta
Cap modified-release 10 mg	30	✓ Ritalin LA
Cap modified-release 20 mg	30	✓ Ritalin LA
Cap modified-release 30 mg	30	✓ Ritalin LA
Cap modified-release 40 mg	30	✓ Ritalin LA

►SA1965 Special Authority for Subsidy

Initial application only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder); and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either:
 - 3.1 Applicant is a paediatrician or psychiatrist; or
 - 3.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing; and
- 4 Either:
 - 4.1 Patient is taking a currently subsidised formulation of methylphenidate hydrochloride (immediate-release or sustained-release) which has not been effective due to significant administration and/or compliance difficulties; or
 - 4.2 There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride.

Renewal only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
 - 2.1 Applicant is a paediatrician or psychiatrist; or
 - 2.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

MODAFINIL – Special Authority see [SA1999 below](#) – Retail pharmacy

Tab 100 mg	29.13	60	✓ Modavigil
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►SA1999 Special Authority for Subsidy

Initial application only from a neurologist or respiratory specialist. Approvals valid for 24 months for applications meeting the following criteria:

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:
 - 2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
 - 2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and
- 3 Either:
 - 3.1 An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialed and discontinued because of intolerable side effects; or
 - 3.2 Methylphenidate and dexamfetamine are contraindicated.

Renewal only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.

Treatments for Dementia

DONEPEZIL HYDROCHLORIDE

* Tab 5 mg	4.34	90	✓ Donepezil-Rex
* Tab 10 mg	6.64	90	✓ Donepezil-Rex

RIVASTIGMINE – Special Authority see [SA1488 below](#) – Retail pharmacy

Patch 4.6 mg per 24 hour	38.00	30	✓ Rivastigmine Patch BNM 5
Patch 9.5 mg per 24 hour	38.00	30	✓ Rivastigmine Patch BNM 10

►SA1488 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The patient has been diagnosed with dementia; and
- 2 The patient has experienced intolerable nausea and/or vomiting from donepezil tablets.

Renewal from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate; and
- 2 The patient has demonstrated a significant and sustained benefit from treatment.

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Treatments for Substance Dependence

BUPRENORPHINE WITH NALOXONE – Special Authority see [SA1203 below](#) – Retail pharmacy

a) No patient co-payment payable

b) Safety medicine; prescriber may determine dispensing frequency

Tab sublingual 2 mg with naloxone 0.5 mg	11.76	28	✓ Buprenorphine Naloxone BNM
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Buprenorphine Naloxone BNM to be Principal Supply on 1 December 2022

Tab sublingual 8 mg with naloxone 2 mg	34.00	28	✓ Buprenorphine Naloxone BNM
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Buprenorphine Naloxone BNM to be Principal Supply on 1 December 2022

►SA1203 Special Authority for Subsidy

Initial application — (Detoxification) from any medical practitioner. Approvals valid for 1 month for applications meeting the following criteria:

All of the following:

- 1 Patient is opioid dependent; and
- 2 Patient is currently engaged with an opioid treatment service approved by the Ministry of Health; and
- 3 Applicant works in an opioid treatment service approved by the Ministry of Health..

Initial application — (Maintenance treatment) from any medical practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient is opioid dependent; and
- 2 Patient will not be receiving methadone; and
- 3 Patient is currently enrolled in an opioid substitution treatment program in a service approved by the Ministry of Health; and
- 4 Applicant works in an opioid treatment service approved by the Ministry of Health.

Renewal — (Detoxification) from any medical practitioner. Approvals valid for 1 month for applications meeting the following criteria:

All of the following:

- 1 Patient is opioid dependent; and
- 2 Patient has previously trialled but failed detoxification with buprenorphine with naloxone with relapse back to opioid use and another attempt is planned; and
- 3 Patient is currently engaged with an opioid treatment service approved by the Ministry of Health; and
- 4 Applicant works in an opioid treatment service approved by the Ministry of Health.

Renewal — (Maintenance treatment) from any medical practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient is or has been receiving maintenance therapy with buprenorphine with naloxone (and is not receiving methadone); and
- 2 Patient is currently enrolled in an opioid substitution program in a service approved by the Ministry of Health; and
- 3 Applicant works in an opioid treatment service approved by the Ministry of Health or is a medical practitioner authorised by the service to manage treatment in this patient.

Renewal — (Maintenance treatment where the patient has previously had an initial application for detoxification) from any medical practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient received but failed detoxification with buprenorphine with naloxone; and
- 2 Maintenance therapy with buprenorphine with naloxone is planned (and patient will not be receiving methadone); and
- 3 Patient is currently enrolled in an opioid substitution program in a service approved by the Ministry of Health; and
- 4 Applicant works in an opioid treatment service approved by the Ministry of Health.

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
BUPROPION HYDROCHLORIDE				
Tab modified-release 150 mg.....	11.00	30	✓	Zyban
DISULFIRAM				
Tab 200 mg.....	236.40	100	✓	Antabuse ^{S29}
NALTREXONE HYDROCHLORIDE – Special Authority see SA1408 below – Retail pharmacy				
Tab 50 mg.....	133.33	30	✓	Nalttraccord

►SA1408 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient is currently enrolled in a recognised comprehensive treatment programme for alcohol dependence; and
- 2 Applicant works in or with a community Alcohol and Drug Service contracted to Health NZ or accredited against the New Zealand Alcohol and Other Drug Sector Standard or the National Mental Health Sector Standard.

Renewal from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Compliance with the medication (prescriber determined); and
- 2 Any of the following:
 - 2.1 Patient is still unstable and requires further treatment; or
 - 2.2 Patient achieved significant improvement but requires further treatment; or
 - 2.3 Patient is well controlled but requires maintenance therapy.

NICOTINE

- a) Nicotine will not be funded in amounts less than 4 weeks of treatment.
 - b) Note: Direct Provision by a pharmacist permitted under the provisions in Part I of Section A.
- | | | | | |
|---|-------|-----|---|-----------------|
| Patch 7 mg – Up to 28 patch available on a PSO..... | 18.14 | 28 | ✓ | Habitrol |
| Patch 7 mg for direct distribution only – [Xpharm]..... | 3.94 | 7 | ✓ | Habitrol |
| Patch 14 mg – Up to 28 patch available on a PSO..... | 19.95 | 28 | ✓ | Habitrol |
| Patch 14 mg for direct distribution only – [Xpharm]..... | 4.52 | 7 | ✓ | Habitrol |
| Patch 21 mg – Up to 28 patch available on a PSO..... | 22.86 | 28 | ✓ | Habitrol |
| Patch 21 mg for direct distribution only – [Xpharm]..... | 5.18 | 7 | ✓ | Habitrol |
| Lozenge 1 mg – Up to 216 loz available on a PSO..... | 19.18 | 216 | ✓ | Habitrol |
| Lozenge 1 mg for direct distribution only – [Xpharm]..... | 3.20 | 36 | ✓ | Habitrol |
| Lozenge 2 mg – Up to 216 loz available on a PSO..... | 21.02 | 216 | ✓ | Habitrol |
| Lozenge 2 mg for direct distribution only – [Xpharm]..... | 3.24 | 36 | ✓ | Habitrol |
| Gum 2 mg (Fruit) – Up to 384 piece available on a PSO..... | 38.21 | 384 | ✓ | Habitrol |
| Gum 2 mg (Fruit) for direct distribution only – [Xpharm]..... | 8.64 | 96 | ✓ | Habitrol |
| Gum 2 mg (Mint) – Up to 384 piece available on a PSO..... | 38.21 | 384 | ✓ | Habitrol |
| Gum 2 mg (Mint) for direct distribution only – [Xpharm]..... | 8.64 | 96 | ✓ | Habitrol |
| Gum 4 mg (Fruit) – Up to 384 piece available on a PSO..... | 44.17 | 384 | ✓ | Habitrol |
| Gum 4 mg (Fruit) for direct distribution only – [Xpharm]..... | 10.01 | 96 | ✓ | Habitrol |
| Gum 4 mg (Mint) – Up to 384 piece available on a PSO..... | 44.17 | 384 | ✓ | Habitrol |
| Gum 4 mg (Mint) for direct distribution only – [Xpharm]..... | 10.01 | 96 | ✓ | Habitrol |

VARENICLINE TARTRATE – Special Authority see [SA1845 on the next page](#) – Retail pharmacy

- a) A maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval, including the starter pack
- b) Varenicline will not be funded in amounts less than 4 weeks of treatment.
- c) The 6-month time period in which a patient can receive a funded 12-week course of varenicline tartrate starts from the date the Special Authority is approved.

Tab 0.5 mg × 11 and 1 mg × 42.....	16.67	53 OP	✓	Varenicline Pfizer
Tab 1 mg.....	17.62	56	✓	Varenicline Pfizer

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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►SA1845 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 5 months for applications meeting the following criteria:

All of the following:

- 1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
- 2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
- 3 Either:
 - 3.1 The patient has tried but failed to quit smoking after at least two separate trials of nicotine replacement therapy, at least one of which included the patient receiving comprehensive advice on the optimal use of nicotine replacement therapy; or
 - 3.2 The patient has tried but failed to quit smoking using bupropion or nortriptyline; and
- 4 The patient has not had a Special Authority for varenicline approved in the last 6 months; and
- 5 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- 6 The patient is not pregnant; and
- 7 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

Renewal from any relevant practitioner. Approvals valid for 5 months for applications meeting the following criteria:

All of the following:

- 1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
- 2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
- 3 It has been 6 months since the patient's previous Special Authority was approved; and
- 4 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- 5 The patient is not pregnant; and
- 6 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

The patient must not have had an approval in the past 6 months.

Notes: a maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval.

This includes the 4-week 'starter' pack.

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Chemotherapeutic Agents

Alkylating Agents

BENDAMUSTINE HYDROCHLORIDE – PCT only – Specialist – Special Authority see [SA2153](#) below

Inj 25 mg vial	77.00	1	✓	Ribomustin
Inj 100 mg vial	308.00	1	✓	Ribomustin
Inj 1 mg for ECP	3.23	1 mg	✓	Baxter

►SA2153 Special Authority for Subsidy

Initial application — (treatment naive CLL) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has Binet stage B or C, or progressive stage A chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is chemotherapy treatment naive; and
- 3 The patient is unable to tolerate toxicity of full-dose FCR; and
- 4 Patient has ECOG performance status 0-2; and
- 5 Patient has a Cumulative Illness Rating Scale (CIRS) score of < 6; and
- 6 Bendamustine is to be administered at a maximum dose of 100 mg/m² on days 1 and 2 every 4 weeks for a maximum of 6 cycles.

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

Initial application — (Indolent, Low-grade lymphomas) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient has indolent low grade NHL requiring treatment; and
- 2 Patient has a WHO performance status of 0-2; and
- 3 Any of the following:
 - 3.1 Both:
 - 3.1.1 Patient is treatment naive; and
 - 3.1.2 Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+); or
 - 3.2 Both:
 - 3.2.1 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen; and
 - 3.2.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
 - 3.3 All of the following:
 - 3.3.1 The patient has not received prior bendamustine therapy; and
 - 3.3.2 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
 - 3.3.3 Patient has had a rituximab treatment-free interval of 12 months or more; or
- 3.4 Bendamustine is to be administered as monotherapy for a maximum of 6 cycles in rituximab refractory patients.

Renewal — (Indolent, Low-grade lymphomas) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Patient is refractory to or has relapsed within 12 months of rituximab in combination with bendamustine; and
 - 1.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or

continued...

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
continued...			
2 Both:			
2.1 Patients have not received a bendamustine regimen within the last 12 months; and			
2.2 Either:			
2.2.1 Both:			
2.2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and			
2.2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more; or			
2.2.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.			
Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ Waldenstrom's macroglobulinaemia.			
Initial application — (Hodgkin's lymphoma*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:			
All of the following:			
1 Patient has Hodgkin's lymphoma requiring treatment; and			
2 Patient has a ECOG performance status of 0-2; and			
3 Patient has received one prior line of chemotherapy; and			
4 Patient's disease relapsed or was refractory following prior chemotherapy; and			
5 Bendamustine is to be administered in combination with gemcitabine and vinorelbine (BeGeV) at a maximum dose of no greater than 90 mg/m ² twice per cycle, for a maximum of four cycles.			
Note: Indications marked with * are unapproved indications.			
BUSULFAN – PCT – Retail pharmacy-Specialist			
Tab 2 mg	89.25	100	✓ Myleran
CARBOPLATIN – PCT only – Specialist			
Inj 10 mg per ml, 45 ml vial.....	32.59	1	✓ DBL Carboplatin
	45.20		✓ Carboplatin Ebewe
	48.50		✓ Carbaccord
Inj 1 mg for ECP	0.10	1 mg	✓ Baxter
CARMUSTINE – PCT only – Specialist			
Inj 100 mg vial	710.00	1	✓ BiCNU
Inj 100 mg for ECP	710.00	100 mg OP	✓ Baxter
CHLORAMBUCIL – PCT – Retail pharmacy-Specialist			
Tab 2 mg	29.06	25	✓ Leukeran FC
CISPLATIN – PCT only – Specialist			
Inj 1 mg per ml, 50 ml vial.....	15.00	1	✓ Cisplatin Ebewe
Inj 1 mg per ml, 100 ml vial.....	21.00	1	✓ Cisplatin Ebewe
	29.66		✓ DBL Cisplatin
Inj 1 mg for ECP	0.31	1 mg	✓ Baxter
CYCLOPHOSPHAMIDE			
Tab 50 mg – PCT – Retail pharmacy-Specialist.....	145.00	50	✓ Cyclonex
Inj 1 g vial – PCT – Retail pharmacy-Specialist.....	35.65	1	✓ Endoxan
	127.80	6	✓ Cytosan
Inj 2 g vial – PCT only – Specialist	71.25	1	✓ Endoxan
Inj 1 mg for ECP – PCT only – Specialist.....	0.04	1 mg	✓ Baxter
IFOSFAMIDE – PCT only – Specialist			
Inj 1 g.....	96.00	1	✓ Holoxan
Inj 2 g.....	180.00	1	✓ Holoxan
Inj 1 mg for ECP	0.10	1 mg	✓ Baxter

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LOMUSTINE – PCT – Retail pharmacy-Specialist				
Cap 10 mg	132.59	20	✓	CeeNU
Cap 40 mg	399.15	20	✓	CeeNU
MELPHALAN				
Tab 2 mg – PCT – Retail pharmacy-Specialist.....	40.70	25	✓	Alkeran
Inj 50 mg – PCT only – Specialist.....	67.80	1	✓	Alkeran
			✓	Alkeran S29 S29
OXALIPLATIN – PCT only – Specialist				
Inj 100 mg vial	25.01	1	✓	Oxaliplatin Actavis 100
	110.00		✓	Oxaliplatin Ebewe
Inj 5 mg per ml, 20 ml vial.....	46.32	1	✓	Oxaliplatin Accord
Inj 1 mg for ECP	0.48	1 mg	✓	Baxter
THIOTEPA – PCT only – Specialist				
Inj 15 mg vial	CBS	1	✓	Bedford S29
			✓	Max Health S29
			✓	THIO-TEPA S29
			✓	Tepadina S29
Inj 100 mg vial	CBS	1	✓	Max Health S29
			✓	Tepadina S29

Antimetabolites

AZACITIDINE – PCT only – Specialist – Special Authority see SA2141 below

Inj 100 mg vial	75.06	1	✓	Azacitidine Dr Reddy's
Inj 1 mg for ECP	0.83	1 mg	✓	Baxter

►SA2141 Special Authority for Subsidy

Initial application only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- Any of the following:
 - The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
 - The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
 - The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
- The patient has performance status (WHO/ECOG) grade 0-2; and
- The patient has an estimated life expectancy of at least 3 months.

Renewal only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- No evidence of disease progression; and
- The treatment remains appropriate and patient is benefitting from treatment.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CALCIUM FOLINATE				
Tab 15 mg – PCT – Retail pharmacy-Specialist.....	114.69	10	✓	DBL Leucovorin Calcium
Inj 3 mg per ml, 1 ml – PCT – Retail pharmacy-Specialist.....	17.10	5	✓	Hospira
Inj 10 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist.....	7.28	1	✓	Calcium Folate Sandoz
			✓	Calcium Folate Sandoz S29 ^{\$29}
Inj 50 mg – PCT – Retail pharmacy-Specialist.....	72.80	10	✓	Leucovorin Pharmacia ^{\$29}
Inj 10 mg per ml, 10 ml vial – PCT only – Specialist	9.49	1	✓	Calcium Folate Sandoz
Inj 100 mg – PCT only – Specialist.....	7.33	1	✓	Calcium Folate Ebewe
	94.90	10	✓	Leucovorin Pharmacia ^{\$29}
Inj 300 mg – PCT only – Specialist.....	22.51	1	✓	Calcium Folate Ebewe
	25.14		✓	Leucovorin DBL ^{\$29}
Inj 10 mg per ml, 35 ml vial – PCT only – Specialist	25.14	1	✓	Calcium Folate Sandoz
			✓	Calcium Folate Sandoz S29 ^{\$29}
Inj 1 g – PCT only – Specialist.....	67.51	1	✓	Calcium Folate Ebewe
Inj 10 mg per ml, 100 ml vial – PCT only – Specialist	72.00	1	✓	Calcium Folate Sandoz
Inj 1 mg for ECP – PCT only – Specialist.....	0.06	1 mg	✓	Baxter
CAPECITABINE – Retail pharmacy-Specialist				
Tab 150 mg	10.00	60	✓	Capercit
Tab 500 mg	49.00	120	✓	Capercit
CLADRIBINE – PCT only – Specialist				
Inj 2 mg per ml, 5 ml.....	749.96	1	✓	Litak ^{\$29}
Inj 1 mg per ml, 10 ml.....	749.96	1	✓	Leustatin
Inj 10 mg for ECP.....	749.96	10 mg OP	✓	Baxter
CYTARABINE				
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist.....	400.00	5	✓	Pfizer
Inj 100 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specialist	41.36	1	✓	Pfizer
Inj 1 mg for ECP – PCT only – Specialist.....	0.25	10 mg	✓	Baxter
Inj 100 mg intrathecal syringe for ECP – PCT only – Specialist.....	80.00	100 mg OP	✓	Baxter
FLUDARABINE PHOSPHATE				
Tab 10 mg – PCT – Retail pharmacy-Specialist.....	412.00	20	✓	Fludara Oral
Inj 50 mg vial – PCT only – Specialist.....	634.00	5	✓	Fludarabine Ebewe
Inj 50 mg for ECP – PCT only – Specialist.....	126.80	50 mg OP	✓	Baxter

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLUOROURACIL				
Inj 50 mg per ml, 20 ml vial – PCT only – Specialist	10.51	1	✓	Fluorouracil Accord
Inj 50 mg per ml, 100 ml vial – PCT only – Specialist	29.44	1	✓	Fluorouracil Accord
Inj 1 mg for ECP – PCT only – Specialist	0.62	100 mg	✓	Baxter
GEMCITABINE HYDROCHLORIDE – PCT only – Specialist				
Inj 1 g, 26.3 ml vial	62.50	1	✓	DBL Gemcitabine
Inj 1 g	15.89	1	✓	Gemcitabine Ebewe
Inj 1 mg for ECP	0.02	1 mg	✓	Baxter
IRINOTECAN HYDROCHLORIDE – PCT only – Specialist				
Inj 20 mg per ml, 5 ml vial	52.57	1	✓	Accord
	71.44		✓	Irinotecan Actavis
				100
	100.00		✓	Irinotecan-Rex
Inj 1 mg for ECP	0.54	1 mg	✓	Baxter
MERCAPTOPYRINE				
Tab 50 mg – PCT – Retail pharmacy-Specialist	25.90	25	✓	Puri-nethol
Puri-nethol to be Principal Supply on 1 December 2022				
Oral suspension 20 mg per ml – Retail pharmacy-Specialist –				
Special Authority see SA1725 below	428.00	100 ml OP	✓	Allmercap
►SA1725 Special Authority for Subsidy				
Initial application only from a paediatric haematologist or paediatric oncologist. Approvals valid for 12 months where the patient requires a total dose of less than one full 50 mg tablet per day.				
Renewal only from a paediatric haematologist or paediatric oncologist. Approvals valid for 12 months where patient still requires a total dose of less than one full 50 mg tablet per day.				
METHOTREXATE				
* Tab 2.5 mg – PCT – Retail pharmacy-Specialist	9.98	90	✓	Trexate
* Tab 10 mg – PCT – Retail pharmacy-Specialist	33.71	90	✓	Trexate
* Inj 2.5 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist	47.50	5	✓	Methotrexate DBL
* Inj 7.5 mg prefilled syringe	14.61	1	✓	Methotrexate
				Sandoz
* Inj 10 mg prefilled syringe	14.66	1	✓	Methotrexate
				Sandoz
* Inj 15 mg prefilled syringe	14.77	1	✓	Methotrexate
				Sandoz
* Inj 20 mg prefilled syringe	14.88	1	✓	Methotrexate
				Sandoz
* Inj 25 mg prefilled syringe	14.99	1	✓	Methotrexate
				Sandoz
* Inj 30 mg prefilled syringe	15.09	1	✓	Methotrexate
				Sandoz
* Inj 25 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist	30.00	5	✓	Methotrexate DBL
				Onco-Vial
* Inj 25 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specialist	45.00	1	✓	DBL Methotrexate
				Onco-Vial
* Inj 100 mg per ml, 10 ml – PCT – Retail pharmacy-Specialist	25.00	1	✓	Methotrexate Ebewe
* Inj 100 mg per ml, 50 ml vial – PCT – Retail				
pharmacy-Specialist	79.99	1	✓	Methotrexate Ebewe
* Inj 1 mg for ECP – PCT only – Specialist	0.06	1 mg	✓	Baxter
* Inj 5 mg intrathecal syringe for ECP – PCT only – Specialist	4.73	5 mg OP	✓	Baxter

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PEMETREXED – PCT only – Specialist – Special Authority see SA1679 below				
Inj 100 mg vial	60.89	1	✓	Juno Pemetrexed
Inj 500 mg vial	217.77	1	✓	Juno Pemetrexed
Inj 1 mg for ECP	0.55	1 mg	✓	Baxter

►SA1679 Special Authority for Subsidy

Initial application — (mesothelioma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

- Both:
- 1 Patient has been diagnosed with mesothelioma; and
 - 2 Pemetrexed to be administered at a dose of 500 mg/m² every 21 days in combination with cisplatin or carboplatin for a maximum of 6 cycles.

Renewal — (mesothelioma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 3 Pemetrexed to be administered at a dose of 500mg/m² every 21 days for a maximum of 6 cycles.

Initial application — (non-small cell lung carcinoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

- Both:
- 1 Patient has locally advanced or metastatic non-squamous non-small cell lung carcinoma; and
 - 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has chemotherapy-naïve disease; and
 - 2.1.2 Pemetrexed is to be administered at a dose of 500 mg/m² every 21 days in combination with cisplatin or carboplatin for a maximum of 6 cycles; or
 - 2.2 All of the following:
 - 2.2.1 Patient has had first-line treatment with platinum based chemotherapy; and
 - 2.2.2 Patient has not received prior funded treatment with pemetrexed; and
 - 2.2.3 Pemetrexed is to be administered at a dose of 500 mg/m² every 21 days for a maximum of 6 cycles.

Renewal — (non-small cell lung carcinoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 3 Pemetrexed is to be administered at a dose of 500mg/m² every 21 days.

THIOGUANINE – PCT – Retail pharmacy-Specialist

Tab 40 mg	126.31	25	✓	Lanvis
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Other Cytotoxic Agents

AMSACRINE – PCT only – Specialist

Inj 50 mg per ml, 1.5 ml ampoule	1,500.00	6	✓	Amsidine S29
	4,736.00		✓	Amsidine S29
Inj 75 mg.....	1,250.00	5	✓	AmsaLyO S29

ANAGRELIDE HYDROCHLORIDE – PCT – Retail pharmacy-Specialist

Cap 0.5 mg.....	1,175.87	100	✓	Agrylin
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ARSENIC TRIOXIDE – PCT only – Specialist

Inj 1 mg per ml, 10 ml vial.....	4,817.00	10	✓	Phenasen
Inj 10 mg for ECP	481.70	10 mg OP	✓	Baxter

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
BLEOMYCIN SULPHATE – PCT only – Specialist				
Inj 15,000 iu, vial.....	185.16	1	✓	DBL Bleomycin Sulfate
Inj 1,000 iu for ECP	14.32	1,000 iu	✓	Baxter
BORTEZOMIB – PCT only – Specialist – Special Authority see SA1889 below				
Inj 3.5 mg vial	105.00	1	✓	Bortezomib Dr-Reddy's
Inj 1 mg for ECP	31.20	1 mg	✓	Baxter
►SA1889 Special Authority for Subsidy				
Initial application — (multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:				
Either:				
1 The patient has symptomatic multiple myeloma; or				
2 The patient has symptomatic systemic AL amyloidosis *.				
Note: Indications marked with * are unapproved indications.				
DACARBAZINE – PCT only – Specialist				
Inj 200 mg vial	62.70	1	✓	DBL Dacarbazine
	580.60	10	✓	Dacarbazine APP ^{S29}
Inj 200 mg for ECP	62.70	200 mg OP	✓	Baxter
DACTINOMYCIN [ACTINOMYCIN D] – PCT only – Specialist				
Inj 0.5 mg vial	255.00	1	✓	Cosmegen
Inj 0.5 mg for ECP	255.00	0.5 mg OP	✓	Baxter
DAUNORUBICIN – PCT only – Specialist				
Inj 2 mg per ml, 10 ml	149.50	1	✓	Pfizer
Inj 20 mg vial	1,495.00	10	✓	Daunorubicin Zentiva ^{S29}
Inj 20 mg for ECP	149.50	20 mg OP	✓	Baxter
DOCETAXEL – PCT only – Specialist				
Inj 20 mg	48.75	1	✓	Docetaxel Sandoz
Inj 10 mg per ml, 8 ml vial	46.89	1	✓	DBL Docetaxel
Inj 20 mg per ml, 4 ml vial	26.95	1	✓	Docetaxel Accord ^{S29}
Inj 80 mg	195.00	1	✓	Docetaxel Sandoz
Inj 1 mg for ECP	0.65	1 mg	✓	Baxter
DOXORUBICIN HYDROCHLORIDE – PCT only – Specialist				
Inj 2 mg per ml, 5 ml vial	10.00	1	✓	Doxorubicin Ebewe
Inj 2 mg per ml, 25 ml vial	11.50	1	✓	Doxorubicin Ebewe
	17.00		✓	Arrow-Doxorubicin
Inj 2 mg per ml, 50 ml vial	23.00	1	✓	Doxorubicin Ebewe
Inj 2 mg per ml, 100 ml vial	65.00	1	✓	Arrow-Doxorubicin
	69.99		✓	Doxorubicin Ebewe
Inj 1 mg for ECP	0.35	1 mg	✓	Baxter
EPIRUBICIN HYDROCHLORIDE – PCT only – Specialist				
Inj 2 mg per ml, 5 ml vial	25.00	1	✓	Epirubicin Ebewe
Inj 2 mg per ml, 25 ml vial	30.00	1	✓	Epirubicin Ebewe
Inj 2 mg per ml, 100 ml vial	99.99	1	✓	Epirubicin Ebewe
Inj 1 mg for ECP	0.50	1 mg	✓	Baxter

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ETOPOSID				
Cap 50 mg – PCT – Retail pharmacy-Specialist	340.73	20	✓	Vepesid
Cap 100 mg – PCT – Retail pharmacy-Specialist	340.73	10	✓	Vepesid
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist	7.90	1	✓	Rex Medical
Inj 1 mg for ECP – PCT only – Specialist	0.09	1 mg	✓	Baxter
ETOPOSID PHOSPHATE – PCT only – Specialist				
Inj 100 mg (of etoposide base)	40.00	1	✓	Etopophos
Inj 1 mg (of etoposide base) for ECP	0.47	1 mg	✓	Baxter
HYDROXYUREA [HYDROXYCARBAMIDE] – PCT – Retail pharmacy-Specialist				
Cap 500 mg	23.82	100	✓	Devatis
IDARUBICIN HYDROCHLORIDE				
Inj 5 mg vial – PCT only – Specialist	109.74	1	✓	Zavedos
Inj 10 mg vial – PCT only – Specialist	233.64	1	✓	Zavedos
Inj 1 mg for ECP – PCT only – Specialist	25.77	1 mg	✓	Baxter
LENALIDOMIDE – Retail pharmacy-Specialist – Special Authority see SA2047 below				
Wastage claimable				
Cap 5 mg	5,122.76	28	✓	Revlimid
Cap 10 mg	4,655.25	21	✓	Revlimid
	6,207.00	28	✓	Revlimid
Cap 15 mg	5,429.39	21	✓	Revlimid
	7,239.18	28	✓	Revlimid
Cap 25 mg	7,627.00	21	✓	Revlimid

►SA2047 Special Authority for Subsidy

Initial application — (Relapsed/refractory disease) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has relapsed or refractory multiple myeloma with progressive disease; and
- 2 Patient has not previously been treated with lenalidomide; and
- 3 Either:
 - 3.1 Lenalidomide to be used as third line* treatment for multiple myeloma; or
 - 3.2 Both:
 - 3.2.1 Lenalidomide to be used as second line treatment for multiple myeloma; and
 - 3.2.2 The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
- 4 Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

Initial application — (Maintenance following first-line autologous stem cell transplant (SCT)) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

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

Renewal — (Relapsed/refractory disease) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and patient is benefitting from treatment.

Renewal — (Maintenance following first line autologous SCT) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

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.

MESNA

Tab 400 mg – PCT – Retail pharmacy-Specialist.....	314.00	50	✓	Uromitexan
Tab 600 mg – PCT – Retail pharmacy-Specialist.....	448.50	50	✓	Uromitexan
Inj 100 mg per ml, 4 ml ampoule – PCT only – Specialist.....	177.45	15	✓	Uromitexan
Inj 100 mg per ml, 10 ml ampoule – PCT only – Specialist.....	407.40	15	✓	Uromitexan
Inj 1 mg for ECP – PCT only – Specialist.....	2.96	100 mg	✓	Baxter

MITOMYCIN C – PCT only – Specialist

Inj 5 mg vial	641.70	1	✓	Accord ^{\$29}
Inj 20 mg vial	3,275.00	1	✓	Omegapharm ^{\$29}
			✓	Teva
Inj 1 mg for ECP	470.75	1 mg	✓	Baxter

MITOZANTRONE – PCT only – Specialist

Inj 2 mg per ml, 10 ml vial.....	97.50	1	✓	Mitozantrone Ebewe
Inj 1 mg for ECP	5.51	1 mg	✓	Baxter

OLAPARIB – Retail pharmacy-Specialist – Special Authority see [SA2148 below](#)

Tab 100 mg	3,701.00	56	✓	Lynparza
Tab 150 mg	3,701.00	56	✓	Lynparza

► [SA2148](#) Special Authority for Subsidy

Initial application — (Ovarian cancer) only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 Patient is currently on treatment with olaparib and met all remaining criteria (criterion 2) below prior to commencing treatment; or
- 2 All of the following:
 - 2.1 Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
 - 2.2 There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
 - 2.3 Either:
 - 2.3.1 All of the following:
 - 2.3.1.1 Patient has newly diagnosed, advanced disease; and
 - 2.3.1.2 Patient has received one line** of previous treatment with platinum-based chemotherapy; and
 - 2.3.1.3 Patient's disease must have experienced a partial or complete response to the first-line platinum-based regimen; or
 - 2.3.2 All of the following:
 - 2.3.2.1 Patient has received at least two lines** of previous treatment with platinum-based chemotherapy; and

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 2.3.2.2 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
- 2.3.2.3 Patient's disease must have experienced a partial or complete response to treatment with the immediately preceding platinum-based regimen; and
- 2.3.2.4 Patient has not previously received funded olaparib treatment; and
- 2.4 Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
- 2.5 Treatment to be administered as maintenance treatment; and
- 2.6 Treatment not to be administered in combination with other chemotherapy.

Renewal — (Ovarian cancer) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from treatment; and
- 2 Either:
 - 2.1 No evidence of progressive disease; or
 - 2.2 Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion; and
- 3 Treatment to be administered as maintenance treatment; and
- 4 Treatment not to be administered in combination with other chemotherapy; and
- 5 Either:
 - 5.1 Both:
 - 5.1.1 Patient has received one line** of previous treatment with platinum-based chemotherapy; and
 - 5.1.2 Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years; or
 - 5.2 Patient has received at least two lines** of previous treatment with platinum-based chemotherapy.

Notes: *Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.

**A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

PACLITAXEL – PCT only – Specialist

Inj 30 mg.....	47.30	5	✓ Paclitaxel Ebewe
Inj 100 mg.....	24.00	1	✓ Paclitaxel Ebewe
	91.67		✓ Paclitaxel Actavis
Inj 150 mg.....	26.69	1	✓ Paclitaxel Ebewe
	137.50		✓ Anzatax
			✓ Paclitaxel Actavis
Inj 300 mg.....	44.00	1	✓ Paclitaxel Ebewe
	275.00		✓ Anzatax
			✓ Paclitaxel Actavis
Inj 1 mg for ECP.....	0.20	1 mg	✓ Baxter

PEGASPARGASE – PCT only – Special Authority see SA1979 below

Inj 750 iu per ml, 5 ml vial.....	3,455.00	1	✓ Oncaspar LYO <small>§29</small>
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►SA1979 Special Authority for Subsidy

Initial application — (Acute lymphoblastic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 1 The patient has newly diagnosed acute lymphoblastic leukaemia; and
- 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol.

Initial application — (Lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where the patient has lymphoma requiring L-asparaginase containing protocols (e.g. SMILE).

Renewal — (Acute lymphoblastic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has relapsed acute lymphoblastic leukaemia; and
- 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol.

PENTOSTATIN [DEOXYCOFORMYCIN] – PCT only – Specialist

Inj 10 mg.....	CBS	1	✓ Nipent ^{\$29}
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PROCARBAZINE HYDROCHLORIDE – PCT – Retail pharmacy-Specialist

Cap 50 mg.....	980.00	50	✓ Natulan ^{\$29}
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TEMOZOLOMIDE – Special Authority see SA1741 below – Retail pharmacy

Cap 5 mg.....	9.13	5	✓ Temaccord
Cap 20 mg.....	16.38	5	✓ Temaccord
	18.30		✓ Apo-Temozolomide
	136.00	14	✓ Accord ^{\$29}
Cap 100 mg.....	35.98	5	✓ Temaccord
	40.20		✓ Apo-Temozolomide
	532.00	14	✓ Accord ^{\$29}
Cap 140 mg.....	50.12	5	✓ Temaccord
	400.00		✓ Amneal ^{\$29}
Cap 180 mg.....	620.00	14	✓ Accord ^{\$29}
Cap 250 mg.....	86.34	5	✓ Temaccord
	688.00		✓ Amneal ^{\$29}

(Accord ^{\$29} Cap 20 mg to be delisted 1 December 2022)

(Accord ^{\$29} Cap 100 mg to be delisted 1 December 2022)

(Amneal ^{\$29} Cap 140 mg to be delisted 1 December 2022)

(Amneal ^{\$29} Cap 250 mg to be delisted 1 December 2022)

➡ **SA1741** Special Authority for Subsidy

Initial application — (high grade gliomas) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Patient has newly diagnosed glioblastoma multiforme; or
 - 1.2 Patient has newly diagnosed anaplastic astrocytoma*; and
- 2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and
- 3 Following concomitant treatment temozolomide is to be used for a maximum of 5 days treatment per cycle, at a maximum dose of 200 mg/m² per day.

Initial application — (neuroendocrine tumours) only from a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with metastatic or unresectable well-differentiated neuroendocrine tumour*; and

continued...

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

- 2 Temozolomide is to be given in combination with capecitabine; and
- 3 Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a maximum dose of 200 mg/m² per day; and
- 4 Temozolomide to be discontinued at disease progression.

Initial application — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 9 months where the patient has relapsed/refractory Ewing's sarcoma.

Renewal — (high grade gliomas) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Patient has glioblastoma multiforme; and
 - 1.2 The treatment remains appropriate and the patient is benefitting from treatment; or
- 2 All of the following:
 - 2.1 Patient has anaplastic astrocytoma*; and
 - 2.2 The treatment remains appropriate and the patient is benefitting from treatment; and
 - 2.3 Adjuvant temozolomide is to be used for a maximum of 24 months.

Renewal — (neuroendocrine tumours) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment.

Renewal — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment.

Note: Indication marked with a * is an unapproved indication. Temozolomide is not subsidised for the treatment of relapsed high grade glioma.

THALIDOMIDE – Retail pharmacy-Specialist – Special Authority see [SA1124 below](#)

Cap 50 mg	378.00	28	✓ Thalomid
Cap 100 mg	756.00	28	✓ Thalomid

► **SA1124 Special Authority for Subsidy**

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 The patient has multiple myeloma; or
- 2 The patient has systemic AL amyloidosis*.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where the patient has obtained a response from treatment during the initial approval period.

Notes: Prescription must be written by a registered prescriber in the thalidomide risk management programme operated by the supplier.

Maximum dose of 400 mg daily as monotherapy or in a combination therapy regimen.

Indication marked with * is an unapproved indication.

TRETINOIN

Cap 10 mg – PCT – Retail pharmacy-Specialist	479.50	100	✓ Vesanoid
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▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
VENETOCLAX – Retail pharmacy-Specialist – Special Authority see SA1868 below				
Tab 14 x 10 mg, 7 x 50 mg, 21 x 100 mg.....	1,771.86	42 OP	✓	Venclexta
Tab 10 mg	95.78	14 OP	✓	Venclexta
Tab 50 mg	239.44	7 OP	✓	Venclexta
Tab 100 mg – Wastage claimable	8,209.41	120	✓	Venclexta

➔ [SA1868](#) Special Authority for Subsidy

Initial application — (relapsed/refractory chronic lymphocytic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 7 months for applications meeting the following criteria:

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.

Renewal — (relapsed/refractory chronic lymphocytic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

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.

Initial application — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

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.

Renewal — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where 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.

VINBLASTINE SULPHATE

Inj 1 mg per ml, 10 ml vial – PCT – Retail pharmacy-Specialist.....	270.37	5	✓	Hospira
Inj 1 mg for ECP – PCT only – Specialist.....	6.00	1 mg	✓	Baxter

VINCRIStINE SULPHATE

Inj 1 mg per ml, 1 ml vial – PCT – Retail pharmacy-Specialist.....	74.52	5	✓	DBL Vincristine Sulfate
Inj 1 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist.....	102.73	5	✓	DBL Vincristine Sulfate
Inj 1 mg for ECP – PCT only – Specialist.....	12.60	1 mg	✓	Baxter

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
VINORELBINE – PCT only – Specialist				
Inj 10 mg per ml, 1 ml vial.....	12.00	1	✓	Navelbine
	42.00		✓	Vinorelbine Ebewe
Inj 10 mg per ml, 5 ml vial.....	56.00	1	✓	Navelbine
	210.00		✓	Vinorelbine Ebewe
	328.65		✓	Sagent ^{S29}
Inj 1 mg for ECP	1.25	1 mg	✓	Baxter
Inj 50 mg for ECP	328.65	50 mg OP	✓	Baxter (Sagent)

Protein-tyrosine Kinase Inhibitors

ALECTINIB – Retail pharmacy-Specialist – Special Authority see [SA1870 below](#)

Wastage claimable

Cap 150 mg	7,935.00	224	✓	Alecensa
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➡SA1870 Special Authority for Subsidy

Initial application only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 6 months for applications meeting the following criteria:

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.

Renewal only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 No evidence of progressive disease according to RECIST criteria; and
- 2 The patient is benefitting from and tolerating treatment.

DASATINIB – Special Authority see [SA1805 below](#) – Retail pharmacy

Wastage claimable

Tab 20 mg	3,774.06	60	✓	Sprycel
Tab 50 mg	6,214.20	60	✓	Sprycel
Tab 70 mg	7,692.58	60	✓	Sprycel

➡SA1805 Special Authority for Subsidy

Initial application only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 Both:
 - 1.1 The patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis or accelerated phase; and
 - 1.2 Maximum dose of 140 mg/day; or
- 2 Both:
 - 2.1 The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL); and
 - 2.2 Maximum dose of 140 mg/day; or
- 3 All of the following:
 - 3.1 The patient has a diagnosis of CML in chronic phase; and
 - 3.2 Maximum dose of 100 mg/day; and
 - 3.3 Any of the following:
 - 3.3.1 Patient has documented treatment failure* with imatinib; or

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 3.3.2 Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib; or
- 3.3.3 Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system; or
- 3.3.4 Patients is enrolled in the KISS study** and requires dasatinib treatment according to the study protocol.

Renewal only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Lack of treatment failure while on dasatinib*; and
- 2 Dasatinib treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Maximum dasatinib dose of 140 mg/day for accelerated or blast phase CML and Ph+ ALL, and 100 mg/day for chronic phase CML.

Note: *treatment failure for CML as defined by Leukaemia Net Guidelines. **Kinase-Inhibition Study with Sprycel Start-up
[https://www.cancertrialsnz.ac.nz/kiss/](https://www.cancertrials.nz.ac.nz/kiss/)

ERLOTINIB – Retail pharmacy-Specialist – Special Authority see [SA2115 below](#)

Tab 100 mg	329.70	30	✓ Alchemy
	764.00		✓ Tarceva
Tab 150 mg	569.70	30	✓ Alchemy
	1,146.00		✓ Tarceva

(Tarceva Tab 100 mg to be delisted 1 February 2023)

(Tarceva Tab 150 mg to be delisted 1 February 2023)

►SA2115 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
- 3 Either:
 - 3.1 Patient is treatment naive; or
 - 3.2 Both:
 - 3.2.1 The patient has discontinued gefitinib due to intolerance; and
 - 3.2.2 The cancer did not progress while on gefitinib; and
- 4 Erlotinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

Renewal — (pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

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 Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

GEFITINIB – Retail pharmacy-Specialist – Special Authority see [SA2116 below](#)

Tab 250 mg	918.00	30	✓ Iressa
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►SA2116 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

- 1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 Either:
 - 2.1 Patient is treatment naive; or
 - 2.2 Both:
 - 2.2.1 The patient has discontinued erlotinib due to intolerance; and
 - 2.2.2 The cancer did not progress whilst on erlotinib; and
- 3 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and
- 4 Gefitinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

Renewal — (pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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

IMATINIB MESILATE

Note: The Glivec brand of imatinib mesilate (supplied by Novartis) remains fully subsidised under Special Authority for patients with unresectable and/or metastatic malignant GIST only, see SA1460 in Section B of the Pharmaceutical Schedule.

Tab 100 mg – [Xpharm] – Special Authority see [SA1460](#)

below	2,400.00	60	✓ Glivec
* Cap 100 mg	58.23	60	✓ Imatinib-Rex
* Cap 400 mg	84.79	30	✓ Imatinib-Rex

►SA1460 Special Authority for Subsidy

Special Authority approved by the CML/GIST Co-ordinator

Notes: Application details may be obtained from Pharmac's website schedule.pharmac.govt.nz/SAForms, and prescriptions should be sent to:

The CML/GIST Co-ordinator Phone: (04) 460 4990
 Pharmac Facsimile: (04) 916 7571
 PO Box 10 254 Email: cmlgistcoordinator@pharmac.govt.nz
 Wellington

Special Authority criteria for GIST – access by application

Funded for patients:

- a) With a diagnosis (confirmed by an oncologist) of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST).
- b) Maximum dose of 400 mg/day.
- c) Applications to be made and subsequent prescriptions can be written by an oncologist.
- d) Initial and subsequent applications are valid for one year. The re-application criterion is an adequate clinical response to the treatment with imatinib (prescriber determined).

LAPATINIB DITOSYLATE – Special Authority see [SA2035 on the next page](#) – Retail pharmacy

Note – no new patients to be initiated on lapatinib ditosylate.

Tab 250 mg	1,899.00	70	✓ Tykerb
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA2035 Special Authority for Subsidy

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on lapatinib; and
- 3 Lapatinib not to be given in combination with trastuzumab; and
- 4 Lapatinib to be discontinued at disease progression.

NILOTINIB – Special Authority see [SA1489 below](#) – Retail pharmacy

Wastage claimable

Cap 150 mg	4,680.00	120	✓ Tasigna
Cap 200 mg	6,532.00	120	✓ Tasigna

►SA1489 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase; and
- 2 Either:
 - 2.1 Patient has documented CML treatment failure* with imatinib; or
 - 2.2 Patient has experienced treatment limiting toxicity with imatinib precluding further treatment with imatinib; and
- 3 Maximum nilotinib dose of 800 mg/day; and
- 4 Subsidised for use as monotherapy only.

Note: *treatment failure as defined by Leukaemia Net Guidelines.

Renewal only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Lack of treatment failure while on nilotinib as defined by Leukaemia Net Guidelines; and
- 2 Nilotinib treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Maximum nilotinib dose of 800 mg/day; and
- 4 Subsidised for use as monotherapy only.

PALBOCICLIB – Retail pharmacy-Specialist – Special Authority see [SA1894 below](#)

Wastage claimable

Tab 75 mg	4,000.00	21	✓ Ibrance
Tab 100 mg	4,000.00	21	✓ Ibrance
Tab 125 mg	4,000.00	21	✓ Ibrance

►SA1894 Special Authority for Subsidy

Initial application only from a medical oncologist or medical practitioner on the recommendation of a Medical oncologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has unresectable locally advanced or metastatic breast cancer; and
- 2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
- 3 Patient has an ECOG performance score of 0-2; and
- 4 Either:
 - second or subsequent line setting
 - 4.1 Disease has relapsed or progressed during prior endocrine therapy; or
 - 4.2 Both:
 - first line setting

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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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 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.

Renewal only from a medical oncologist or medical practitioner on the recommendation of a Medical oncologist. Approvals valid for 12 months for applications meeting the following criteria:

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.

PAZOPANIB – Special Authority see [SA1190 below](#) – Retail pharmacy

Tab 200 mg	1,334.70	30	✓ Votrient
Tab 400 mg	2,669.40	30	✓ Votrient

► **SA1190** Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
 - 2.1 The patient is treatment naive; or
 - 2.2 The patient has only received prior cytokine treatment; or
 - 2.3 Both:
 - 2.3.1 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
 - 2.3.2 The cancer did not progress whilst on sunitinib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and
The patient has intermediate or poor prognosis defined as:
- 5 Any of the following:
 - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
 - 5.2 Haemoglobin level < lower limit of normal; or
 - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
 - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
 - 5.5 Karnofsky performance score of less than or equal to 70; or
 - 5.6 2 or more sites of organ metastasis; and
- 6 Pazopanib to be used for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment.

Notes: Pazopanib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
RUXOLITINIB – Special Authority see SA1890 below – Retail pharmacy				
Wastage claimable				
Tab 5 mg	2,500.00	56	✓ Jakavi	
Tab 10mg	5,000.00	56	✓ Jakavi	
Tab 15 mg	5,000.00	56	✓ Jakavi	
Tab 20 mg	5,000.00	56	✓ Jakavi	

►SA1890 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

- 1 The patient has primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis; and
- 2 Either:
 - 2.1 A classification of risk of intermediate-2 or high-risk myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; or
 - 2.2 Both:
 - 2.2.1 A classification of risk of intermediate-1 myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; and
 - 2.2.2 Patient has severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; and
- 3 A maximum dose of 20 mg twice daily is to be given.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 A maximum dose of 20 mg twice daily is to be given.

SUNITINIB – Special Authority see [SA2117 below](#) – Retail pharmacy

Cap 12.5 mg	208.38	28	✓ Sunitinib Pfizer
Cap 25 mg	416.77	28	✓ Sunitinib Pfizer
Cap 50 mg	694.62	28	✓ Sunitinib Pfizer

►SA2117 Special Authority for Subsidy

Initial application — (RCC) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
 - 2.1 The patient is treatment naive; or
 - 2.2 The patient has only received prior cytokine treatment; or
 - 2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval; or
 - 2.4 Both:
 - 2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and
 - 2.4.2 The cancer did not progress whilst on pazopanib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and
The patient has intermediate or poor prognosis defined as:
- 5 Any of the following:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

- 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
- 5.2 Haemoglobin level < lower limit of normal; or
- 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
- 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
- 5.5 Karnofsky performance score of less than or equal to 70; or
- 5.6 2 or more sites of organ metastasis; and

6 Sunitinib to be used for a maximum of 2 cycles.

Initial application — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and
- 2 Either:
 - 2.1 The patient's disease has progressed following treatment with imatinib; or
 - 2.2 The patient has documented treatment-limiting intolerance, or toxicity to, imatinib.

Renewal — (RCC) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Notes: Sunitinib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6

Renewal — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 6 months for applications meeting the following criteria:

Both:

The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:

- 1 Any of the following:
 - 1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or
 - 1.2 The patient has had a partial response (a decrease in size of 10% or more or decrease in tumour density in Hounsfield Units (HU) of 15% or more on CT and no new lesions and no obvious progression of non measurable disease); or
 - 1.3 The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of 10% or more and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

Renewal — (GIST pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal (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 Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Endocrine Therapy

For GnRH ANALOGUES – refer to HORMONE PREPARATIONS, Tropic Hormones, [page 83](#)

ABIRATERONE ACETATE – Retail pharmacy-Specialist – Special Authority see [SA2118 below](#)

Wastage claimable

Tab 250 mg	4,276.19	120	✓ Zytiga
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➔SA2118 Special Authority for Subsidy

Initial application only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months for applications meeting the following criteria: 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.

Renewal — (abiraterone acetate) only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Significant decrease in serum PSA from baseline; and
- 2 No evidence of clinical disease progression; and
- 3 No initiation of taxane chemotherapy with abiraterone; and
- 4 The treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
- 2 Abiraterone acetate to be discontinued at progression; and
- 3 No initiation of taxane chemotherapy with abiraterone; and
- 4 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

BICALUTAMIDE

Tab 50 mg	4.21	28	✓ Binarex
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FLUTAMIDE

Tab 250 mg	107.55	90	✓ Prostaticur ^{\$29}
	119.50	100	✓ Flutamin

FULVESTRANT – Retail pharmacy-Specialist – Special Authority see [SA1895 on the next page](#)

Inj 50 mg per ml, 5 ml prefilled syringe	1,068.00	2	✓ Faslodex
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1895 Special Authority for Subsidy

Initial application only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist.

Approvals valid for 6 months for applications meeting the following criteria:

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.

Renewal only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Treatment remains appropriate and patient is benefitting from treatment; and
- 2 Treatment to be given at a dose of 500 mg monthly; and
- 3 There is no evidence of disease progression.

MEGESTROL ACETATE – Subsidy by endorsement

Subsidy by endorsement – Subsidised for patients who were taking megestrol acetate prior to 1 August 2021 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of megestrol acetate.

Tab 160 mg	48.80	30	✓ Megace <small>\$29</small>
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(Megace \$29 Tab 160 mg to be delisted 1 February 2023)

OCTREOTIDE

Inj 50 mcg per ml, 1 ml ampoule	27.58	5	✓ Max Health
Inj 100 mcg per ml, 1 ml ampoule	32.71	5	✓ Octreotide GH <small>\$29</small>
Inj 500 mcg per ml, 1 ml ampoule	113.10	5	✓ Max Health

OCTREOTIDE LONG-ACTING – Special Authority see SA2119 below – Retail pharmacy

Inj depot 10 mg prefilled syringe.....	439.97	1	✓ Octreotide Depot Teva
Inj depot 20 mg prefilled syringe.....	647.03	1	✓ Octreotide Depot Teva
Inj depot 30 mg prefilled syringe.....	718.55	1	✓ Octreotide Depot Teva

►SA2119 Special Authority for Subsidy

Initial application — (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 2 months for applications meeting the following criteria:

All of the following:

- 1 The patient has nausea* and vomiting* due to malignant bowel obstruction*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed; and
- 3 Octreotide to be given at a maximum dose 1500 mcg daily for up to 4 weeks.

Note: Indications marked with * are unapproved indications.

Renewal — (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 3 months where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (Acromegaly) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

Both:

- 1 The patient has acromegaly; and
- 2 Any of the following:
 - 2.1 Treatment with surgery, radiotherapy and a dopamine agonist has failed; or
 - 2.2 Treatment with octreotide is for an interim period while awaiting the effects of radiotherapy and a dopamine agonist has failed; or
 - 2.3 The patient is unwilling, or unable, to undergo surgery and/or radiotherapy.

Renewal — (Acromegaly) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 IGF1 levels have decreased since starting octreotide; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: In patients with Acromegaly octreotide treatment should be discontinued if IGF1 levels have not decreased after 3 months treatment. In patients treated with radiotherapy octreotide treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Octreotide treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following octreotide treatment withdrawal for at least 4 weeks

Renewal — (Acromegaly - pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

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 Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

Initial application — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 VIPomas and Glucagonomas - for patients who are seriously ill in order to improve their clinical state prior to definitive surgery; or
- 2 Both:
 - 2.1 Gastrinoma; and
 - 2.2 Either:
 - 2.2.1 Patient has failed surgery; or
 - 2.2.2 Patient in metastatic disease after H2 antagonists (or proton pump inhibitors) have failed; or
- 3 Both:
 - 3.1 Insulinomas; and
 - 3.2 Surgery is contraindicated or has failed; or
- 4 For pre-operative control of hypoglycaemia and for maintenance therapy; or
- 5 Both:
 - 5.1 Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis); and
 - 5.2 Disabling symptoms not controlled by maximal medical therapy.

Note: The use of octreotide in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded as a Special Authority item

Renewal — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (pre-operative acromegaly) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has acromegaly; and

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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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- 2 Patient has a large pituitary tumour, greater than 10 mm at its widest; and
- 3 Patient is scheduled to undergo pituitary surgery in the next six months.

TAMOXIFEN CITRATE

* Tab 10 mg	15.00	60	✓	<u>Tamoxifen Sandoz</u>
* Tab 20 mg	6.65	60	✓	<u>Tamoxifen Sandoz</u>

Aromatase Inhibitors

ANASTROZOLE

* Tab 1 mg	4.55	30	✓	<u>Anatrole</u>
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EXEMESTANE

* Tab 25 mg	14.50	30	✓	<u>Pfizer Exemestane</u>
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LETROZOLE

* Tab 2.5 mg	5.84	30	✓	<u>Letrole</u>
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Immunosuppressants

Cytotoxic Immunosuppressants

AZATHIOPRINE

* Tab 25 mg	7.35	60	✓	<u>Azamun</u>
* Tab 50 mg	7.60	100	✓	<u>Azamun</u>
* Inj 50 mg vial	199.00	1	✓	<u>Imuran</u>

(Imuran Inj 50 mg vial to be delisted 1 January 2023)

MYCOPHENOLATE MOFETIL

Tab 500 mg	35.90	50	✓	<u>Cellcept</u>
Cap 250 mg	35.90	100	✓	<u>Cellcept</u>
Powder for oral liq 1 g per 5 ml – Subsidy by endorsement	187.25	165 ml OP	✓	<u>Cellcept</u>

Mycophenolate powder for oral liquid is subsidised only for patients unable to swallow tablets and capsules, and when the prescription is endorsed accordingly.

Fusion Proteins

ETANERCEPT – Special Authority see [SA2103 below](#) – Retail pharmacy

Inj 25 mg	690.00	4	✓	<u>Enbrel</u>
Inj 25 mg autoinjector	690.00	4	✓	<u>Enbrel</u>
Inj 50 mg autoinjector	1,050.00	4	✓	<u>Enbrel</u>
Inj 50 mg prefilled syringe	1,050.00	4	✓	<u>Enbrel</u>

►SA2103 Special Authority for Subsidy

Initial application — (adult-onset Still's disease) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

1.1 Either:

1.1.1 The patient has had an initial Special Authority approval for adalimumab for adult-onset Still's disease (AOSD); or

1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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1.2 Either:

- 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or tocilizumab; or
- 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD; or

2 All of the following:

- 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
- 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
- 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Either:

- 1.1 Applicant is a rheumatologist; or
- 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and

2 The patient has a sustained improvement in inflammatory markers and functional status.

Initial application — (ankylosing spondylitis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or

2 All of the following:

- 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and
- 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
- 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
- 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
- 2.5 Either:
 - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
 - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and

2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm

25-34 years - Male: 7.5 cm; Female: 5.5 cm

35-44 years - Male: 6.5 cm; Female: 4.5 cm

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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45-54 years - Male: 6.0 cm; Female: 5.0 cm

55-64 years - Male: 5.5 cm; Female: 4.0 cm

65-74 years - Male: 4.0 cm; Female: 4.0 cm

75+ years - Male: 3.0 cm; Female: 2.5 cm

Renewal — (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Initial application — (polyarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for polyarticular course JIA; or
- 2 All of the following:
 - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
 - 2.3 Any of the following:
 - 2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Renewal — (polyarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Initial application — (oligoarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA); and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA; or

2 All of the following:

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

Renewal — (oligoarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

Initial application — (psoriatic arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab or secukinumab for psoriatic arthritis; and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab or secukinumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab or secukinumab for psoriatic arthritis; or

2 All of the following:

- 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
- 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
- 2.4 Either:

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
- 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2.5 Any of the following:
 - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
 - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Either:
 - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has pyoderma gangrenosum*; and
- 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
- 3 A maximum of 8 doses.

Note: Indications marked with * are unapproved indications.

Renewal — (pyoderma gangrenosum) only from a dermatologist or Practitioner on the recommendation of a dermatologist.

Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment; and
- 3 A maximum of 8 doses.

Initial application — (Arthritis - rheumatoid) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects; or
 - 1.2.2 The patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis; or
- 2 All of the following:

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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
- 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
- 2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses unless contraindicated); and
- 2.5 Either:
 - 2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
 - 2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and
- 2.6 Either:
 - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
 - 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

Renewal — (Arthritis - rheumatoid) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
 - 2.1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Initial application — (severe chronic plaque psoriasis) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
 - 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 2.3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 2.4 The most recent PASI or DLQI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a dermatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 2.1.2 Either:
 - 2.1.2.1 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
 - 2.1.2.2 Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
 - 2.2 Both:
 - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 2.2.2 Either:
 - 2.2.2.1 Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
 - 2.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

Initial application — (undifferentiated spondyloarthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day (or maximum tolerated dose); and
- 4 Patient has tried and not responded to at least three months of leflunomide at a dose of up to 20 mg daily (or maximum tolerated dose); and
- 5 Any of the following:

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

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- 5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
- 5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour measured no more than one month prior to the date of this application; or
- 5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Note: Indications marked with * are unapproved indications.

Renewal — (undifferentiated spondyloarthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Either:
 - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician; and
- 3 Etanercept to be administered at doses no greater than 50 mg dose every 7 days.

Immune Modulators

ANTITHYMOCYTE GLOBULIN (EQUINE) – PCT only – Specialist

Inj 50 mg per ml, 5 ml.....	2,774.48	5	✓ ATGAM
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BACILLUS CALMETTE-GUERIN (BCG) VACCINE – PCT only – Specialist

Subsidised only for bladder cancer.

Inj 2-8 x 100 million CFU.....	149.37	1	✓ OncoTICE
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Inj 40 mg per ml, vial.....	176.90	3	✓ SII-Onco-BCG ^{\$29}
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Monoclonal Antibodies

ADALIMUMAB (AMGEVITA) – Special Authority see [SA2142 below](#) – Retail pharmacy

Inj 20 mg per 0.4 ml prefilled syringe.....	190.00	1	✓ Amgevita
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Inj 40 mg per 0.8 ml prefilled pen.....	375.00	2	✓ Amgevita
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Inj 40 mg per 0.8 ml prefilled syringe.....	375.00	2	✓ Amgevita
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➔ [SA2142](#) Special Authority for Subsidy

Initial application — (Behcet's disease - severe) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Both:
 - 2.1 The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and
 - 2.2 Either:
 - 2.2.1 The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s); or
 - 2.2.2 The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not

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responded adequately to two or more treatments appropriate for the particular symptom(s).

Note: Indications marked with * are unapproved indications.

Initial application — (Hidradenitis suppurativa) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
 - 2.2 Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or has demonstrated intolerance to or has contraindications for systemic antibiotics; and
 - 2.3 Patient has 3 or more active lesions; and
 - 2.4 The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

Renewal — (Hidradenitis suppurativa) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
- 2 The patient has a DLQI improvement of 4 or more from baseline.

Initial application — (Plaque psoriasis - severe chronic) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
 - 2.1.2 Either:
 - 2.1.2.1 Patient has experienced intolerable side effects; or
 - 2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
 - 2.2 All of the following:
 - 2.2.1 Either:
 - 2.2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
 - 2.2.2 Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
 - 2.2.3 A PASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

Renewal — (Plaque psoriasis - severe chronic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 1.2 Either:

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

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- 1.2.1 The patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre treatment baseline value; or
- 1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or

2 Both:

- 2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
- 2.2 Either:
 - 2.2.1 The patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
 - 2.2.2 The patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre treatment baseline value.

Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Both:
 - 2.1 Patient has pyoderma gangrenosum*; and
 - 2.2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and has not received an adequate response.

Note: Indications marked with * are unapproved indications.

Initial application — (Crohn's disease - adults) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has severe active Crohn's disease; and
 - 2.2 Any of the following:
 - 2.2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
 - 2.2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
 - 2.2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
 - 2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
 - 2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on adalimumab; or
- 2 CDAI score is 150 or less, or HBI is 4 or less; or
- 3 The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

Initial application — (Crohn's disease - children) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:

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- 2.1 Paediatric patient has active Crohn's disease; and
- 2.2 Either:
 - 2.2.1 Patient has a PCDAI score of greater than or equal to 30; or
 - 2.2.2 Patient has extensive small intestine disease; and
- 2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
- 2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal — (Crohn's disease - children) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
- 2 PCDAI score is 15 or less; or
- 3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.

Initial application — (Crohn's disease - fistulising) only from a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has confirmed Crohn's disease; and
 - 2.2 Any of the following:
 - 2.2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
 - 2.2.2 Patient has one or more rectovaginal fistula(e); or
 - 2.2.3 Patient has complex peri-anal fistula; and
 - 2.3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

Renewal — (Crohn's disease - fistulising) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 The number of open draining fistulae have decreased from baseline by at least 50%; or
- 2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

Initial application — (Ocular inflammation - chronic) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
 - 2.2 Both:
 - 2.2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
 - 2.2.2 Any of the following:
 - 2.2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
 - 2.2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
 - 2.2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

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Renewal — (Ocular inflammation - chronic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 12 weeks' initial treatment; or
- 2 Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Initial application — (Ocular inflammation - severe) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
 - 2.2 Both:
 - 2.2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
 - 2.2.2 Any of the following:
 - 2.2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
 - 2.2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
 - 2.2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

Renewal — (Ocular inflammation - severe) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses; or
- 2 Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Initial application — (ankylosing spondylitis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
 - 2.1.2 Either:
 - 2.1.2.1 The patient has experienced intolerable side effects; or
 - 2.1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
 - 2.2 All of the following:
 - 2.2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
 - 2.2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
 - 2.2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and

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2.2.4 Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and

2.2.5 Either:

2.2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or

2.2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender; and

2.2.6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment and is no more than 1 month old at the time of application.

Renewal — (ankylosing spondylitis) from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

Initial application — (Arthritis - oligoarticular course juvenile idiopathic) only from a named specialist or rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

2 Either:

2.1 Both:

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

2.1.2 Either:

2.1.2.1 Patient has experienced intolerable side effects; or

2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA; or

2.2 All of the following:

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

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

2.2.3 Either:

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

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

Renewal — (Arthritis - oligoarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

1 Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or

2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initial application — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist or rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

2 Either:

2.1 Both:

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- 2.1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
- 2.1.2 Either:
 - 2.1.2.1 Patient has experienced intolerable side effects; or
 - 2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
- 2.2 All of the following:
 - 2.2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
 - 2.2.3 Any of the following:
 - 2.2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Renewal — (Arthritis - polyarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

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

Initial application — (Arthritis - psoriatic) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
 - 2.1.2 Either:
 - 2.1.2.1 The patient has experienced intolerable side effects; or
 - 2.1.2.2 The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis; or
 - 2.2 All of the following:
 - 2.2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
 - 2.2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
 - 2.2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
 - 2.2.4 Either:
 - 2.2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
 - 2.2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
 - 2.2.5 Any of the following:
 - 2.2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.2.5.2 Patient has an ESR greater than 25 mm per hour; or

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2.2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (Arthritis - psoriatic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Following initial treatment, the patient has at least a 50% decrease in swollen joint count from baseline and a clinically significant response in the opinion of the physician; or
- 2 Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response in the opinion of the treating physician.

Initial application — (Arthritis - rheumatoid) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
 - 2.1.2 Either:
 - 2.1.2.1 The patient has experienced intolerable side effects; or
 - 2.1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or
 - 2.2 All of the following:
 - 2.2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is CCP antibody positive) for six months duration or longer; and
 - 2.2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
 - 2.2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated); and
 - 2.2.5 Either:
 - 2.2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
 - 2.2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and
 - 2.2.6 Either:
 - 2.2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
 - 2.2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

Renewal — (Arthritis - rheumatoid) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

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Initial application — (Still's disease - adult-onset (AOSD)) only from a rheumatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and
 - 2.1.2 Either:
 - 2.1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
 - 2.1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
 - 2.2 All of the following:
 - 2.2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
 - 2.2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate; and
 - 2.2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initial application — (ulcerative colitis) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has histologically confirmed ulcerative colitis; and
 - 2.2 Either:
 - 2.2.1 Patient's SCCAI score is greater than or equal to 4; or
 - 2.2.2 Patient's PUCAI score is greater than or equal to 65; and
 - 2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids; and
 - 2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on adalimumab; or
- 2 The PUCAI score has reduced by 30 points or more from the PUCAI score since initiation on adalimumab.

Initial application — (undifferentiated spondyloarthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
 - 2.2 Patient has tried and not responded to at least three months of each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and
 - 2.3 Any of the following:
 - 2.3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

- 2.3.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Note: Indications marked with * are unapproved indications

Renewal — (undifferentiated spondyloarthritis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician.

Initial application — (inflammatory bowel arthritis – axial) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
 - 2.2 Patient has axial inflammatory pain for six months or more; and
 - 2.3 Patient is unable to take NSAIDs; and
 - 2.4 Patient has bilateral sacroiliitis demonstrated by radiological imaging; and
 - 2.5 Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
 - 2.6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment.

Renewal — (inflammatory bowel arthritis – axial) from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

Initial application — (inflammatory bowel arthritis – peripheral) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
 - 2.2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
 - 2.3 Patient has tried and not responded to at least three months of methotrexate, or azathioprine at a maximum tolerated dose; and
 - 2.4 Patient has tried and not responded to at least three months of sulfasalazine at a maximum tolerated dose; and
 - 2.5 Any of the following:
 - 2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.5.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
 - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (inflammatory bowel arthritis – peripheral) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 1 Following initial treatment, patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 Patient demonstrates at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

ADALIMUMAB (HUMIRA) – Special Authority see [SA2101 below](#) – Retail pharmacy

Inj 20 mg per 0.2 ml prefilled syringe.....	1,599.96	2	✓	Humira
Inj 20 mg per 0.4 ml prefilled syringe.....	1,599.96	2	✓	Humira
Inj 40 mg per 0.8 ml prefilled pen	1,599.96	2	✓	HumiraPen
Inj 40 mg per 0.8 ml prefilled syringe.....	1,599.96	2	✓	Humira

(Humira Inj 20 mg per 0.4 ml prefilled syringe to be delisted 1 December 2022)

➔SA2101 Special Authority for Subsidy

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 The patient has a sustained improvement in inflammatory markers and functional status.

Renewal — (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (chronic ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 The patient has had a good clinical response following 12 weeks' initial treatment; or
 - 1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
 - 1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if adalimumab is withdrawn.

Renewal — (Crohn's disease - adults) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

All of the following:

- 1 Either:
 - 1.1 Applicant is a gastroenterologist; or
 - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Either:
 - 2.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
 - 2.1.2 CDAI score is 150 or less; or
 - 2.2 Both:
 - 2.2.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
 - 2.2.2 Applicant to indicate the reason that CDAI score cannot be assessed; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Crohn's disease - children) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a gastroenterologist; or
 - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Either:
 - 2.1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
 - 2.1.2 PCDAI score is 15 or less; or
 - 2.2 Both:
 - 2.2.1 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
 - 2.2.2 Applicant to indicate the reason that PCDAI score cannot be assessed; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 Applicant is a gastroenterologist; or
 - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
 - 2.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

Renewal — (hidradenitis suppurativa) only from a dermatologist or Practitioner on the recommendation of a dermatologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
- 2 The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline; and
- 3 Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.

Renewal — (polyarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

Renewal — (oligoarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

Renewal — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (pyoderma gangrenosum) only from a dermatologist or Practitioner on the recommendation of a dermatologist.

Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment; and
- 3 A maximum of 8 doses.

Renewal — (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 3 Either:
 - 3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 4 Either:
 - 4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
 - 4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Renewal — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a dermatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 2.1.2 Either:
 - 2.1.2.1 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
 - 2.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
 - 2.2 Both:
 - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 2.2.2 Either:
 - 2.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
 - 2.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value; and

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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: A treatment course is defined as a minimum of 12 weeks adalimumab treatment

Renewal — (severe ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

1 Any of the following:

- 1.1 The patient has had a good clinical response following 3 initial doses; or
- 1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if adalimumab is withdrawn.

AFLIBERCEPT – Special Authority see [SA1772 below](#) – Retail pharmacy

Inj 40 mg per ml, 0.1 ml vial.....	1,250.00	1	✓ Eylea
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► [SA1772](#) Special Authority for Subsidy

Initial application — (wet age related macular degeneration) only from an ophthalmologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1 All of the following:

1.1 Any of the following:

- 1.1.1 Wet age-related macular degeneration (wet AMD); or
- 1.1.2 Polypoidal choroidal vasculopathy; or
- 1.1.3 Choroidal neovascular membrane from causes other than wet AMD; and

1.2 Either:

- 1.2.1 The patient has developed severe endophthalmitis or severe posterior uveitis following treatment with bevacizumab; or
- 1.2.2 There is worsening of vision or failure of retina to dry despite three intraocular injections of bevacizumab four weeks apart; and

1.3 There is no structural damage to the central fovea of the treated eye; and

1.4 Patient has not previously been treated with ranibizumab for longer than 3 months; or

2 Either:

2.1 Patient has current approval to use ranibizumab for treatment of wAMD and was found to be intolerant to ranibizumab within 3 months; or

2.2 Patient has previously* (*before June 2018) received treatment with ranibizumab for wAMD and disease was stable while on treatment.

Initial application — (diabetic macular oedema) only from an ophthalmologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has centre involving diabetic macular oedema (DMO); and
- 2 Patient's disease is non responsive to 4 doses of intravitreal bevacizumab when administered 4-6 weekly; and
- 3 Patient has reduced visual acuity between 6/9 – 6/36 with functional awareness of reduction in vision; and
- 4 Patient has DMO within central OCT (ocular coherence tomography) subfield > 350 micrometers; and
- 5 There is no centre-involving sub-retinal fibrosis or foveal atrophy.

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Renewal — (wet age related macular degeneration) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Documented benefit must be demonstrated to continue; and
- 2 Patient's vision is 6/36 or better on the Snellen visual acuity score; and
- 3 There is no structural damage to the central fovea of the treated eye.

Renewal — (diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 There is stability or two lines of Snellen visual acuity gain; and
- 2 There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid); and
- 3 Patient's vision is 6/36 or better on the Snellen visual acuity score; and
- 4 There is no centre-involving sub-retinal fibrosis or foveal atrophy; and
- 5 After each consecutive 12 months treatment with (2nd line anti-VEGF agent), patient has retrialled with at least one injection of bevacizumab and had no response.

BENRALIZUMAB – Special Authority see [SA2151 below](#) – Retail pharmacy

Inj 30 mg per ml, 1 ml prefilled pen	3,539.00	1	✓ Fasenra
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► **SA2151** Special Authority for Subsidy

Initial application — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
- 3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
- 4 Patient has a blood eosinophil count of greater than 0.5×10^9 cells/L in the last 12 months; and
- 5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long-acting beta-2 agonist, or budesonide/formoterol as part of the anti-inflammatory reliever therapy plus maintenance 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 Treatment is not to be used in combination with subsidised mepolizumab; and
- 8 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; and
- 9 Either:
 - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
 - 9.2 Both:
 - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
 - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

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▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

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 benralizumab; or
 - 2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

CASIRIVIMAB AND IMDEVIMAB – [Xpharm] – Special Authority see [SA2096 below](#)

Inj 120 mg per ml casirivimab, 11.1 ml vial (1) and inj 120 mg per ml imdevimab, 11.1 ml vial (1).....	0.00	1 OP	✓	Ronapreve
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➔ [SA2096](#) Special Authority for Subsidy

Initial application — (Treatment of profoundly immunocompromised patients) from any relevant practitioner. Approvals valid for 2 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed (or probable) COVID-19; and
- 2 The patient is in the community with mild to moderate disease severity*; and
- 3 Patient is profoundly immunocompromised** and is at risk of not having mounted an adequate response to vaccination against COVID-19 or is unvaccinated; and
- 4 Patient's symptoms started within the last 10 days; and
- 5 Patient is not receiving high flow oxygen or assisted/mechanical ventilation; and
- 6 Casirivimab and imdevimab is to be administered at a maximum dose of no greater than 2,400 mg.

Notes: * Mild to moderate disease severity as described on the [Ministry of Health Website](#)

** Examples include B-cell depletive illnesses or patients receiving treatment that is B-Cell depleting.

CETUXIMAB – PCT only – Specialist – Special Authority see [SA1697 below](#)

Inj 5 mg per ml, 20 ml vial.....	364.00	1	✓	Erbitux
Inj 5 mg per ml, 100 ml vial.....	1,820.00	1	✓	Erbitux
Inj 1 mg for ECP.....	3.82	1 mg	✓	Baxter

➔ [SA1697](#) Special Authority for Subsidy

Initial application only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced, non-metastatic, squamous cell cancer of the head and neck; and
- 2 Patient is contraindicated to, or is intolerant of, cisplatin; and
- 3 Patient has good performance status; and
- 4 To be administered in combination with radiation therapy.

GEMTUZUMAB OZOGAMICIN – PCT only – Specialist – Special Authority see [SA2136 below](#)

Inj 5 mg vial.....	12,973.00	1	✓	Mylotarg
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➔ [SA2136](#) Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has not received prior chemotherapy for this condition; and
- 2 Patient has de novo CD33-positive acute myeloid leukaemia; and
- 3 Patient does not have acute promyelocytic leukaemia; and
- 4 Gemtuzumab ozogamicin will be used in combination with standard anthracycline and cytarabine (AraC); and

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 5 Patient is being treated with curative intent; and
- 6 Patient's disease risk has been assessed by cytogenetic testing to be good or intermediate; and
- 7 Patient must be considered eligible for standard intensive remission induction chemotherapy with daunorubicin and cytarabine (AraC); and
- 8 Gemtuzumab ozogamicin to be funded for one course only; and
- 9 Either:
 - 9.1 Gemtuzumab ozogamicin to be administered as one dose at 3 mg per m² body surface area; or
 - 9.2 Up to 10 mg of gemtuzumab ozogamicin to be administered.

Note: Acute myeloid leukaemia excludes acute promyelocytic leukaemia and acute myeloid leukaemia that is secondary to another haematological disorder (eg myelodysplasia or myeloproliferative disorder).

INFLIXIMAB – PCT only – Special Authority see [SA2082 below](#)

Inj 100 mg.....	806.00	1	✓ Remicade
Inj 1 mg for ECP	8.29	1 mg	✓ Baxter

►SA2082 Special Authority for Subsidy

Initial application — (Crohn's disease (adults)) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe active Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
 - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
 - 2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate; and
- 5 Patient must be reassessed for continuation after 3 months of therapy.

Renewal — (Crohn's disease (adults)) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on infliximab; or
 - 1.2 CDAI score is 150 or less; or
 - 1.3 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (Crohn's disease (children)) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Paediatric patient has severe active Crohn's disease; and
- 2 Either:
 - 2.1 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
 - 2.2 Patient has extensive small intestine disease; and

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- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate; and
- 5 Patient must be reassessed for continuation after 3 months of therapy.

Renewal — (Crohn's disease (children)) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
 - 1.2 PCDAI score is 15 or less; or
 - 1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (Graft vs host disease) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has steroid-refractory acute graft vs. host disease of the gut.

Initial application — (Pulmonary sarcoidosis) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has life-threatening pulmonary sarcoidosis diagnosed by a multidisciplinary team that is refractory to other treatments.

Initial application — (acute severe fulminant ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient has acute, severe fulminant ulcerative colitis; and
- 2 Treatment with intravenous or high dose oral corticosteroids has not been successful.

Initial application — (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
 - 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

Renewal — (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Following 12 weeks of infliximab treatment, BASDAI has improved by 4 or more points from pre-infliximab baseline on a 10 point scale, or by 50%, whichever is less; and
- 2 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 3 Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks.

Initial application — (chronic ocular inflammation) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or

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- 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for chronic ocular inflammation; or

2 Both:

- 2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
- 2.2 Any of the following:
 - 2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
 - 2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
 - 2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

Renewal — (chronic ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses; or
- 2 Following each 12 month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

Initial application — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient has confirmed Crohn's disease; and
- 2 Either:
 - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
 - 2.2 Patient has one or more rectovaginal fistula(e).

Renewal — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
 - 1.2 There has been a marked reduction in drainage of all fistula(e) from baseline (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (neurosarcoidosis) only from a neurologist or Practitioner on the recommendation of a neurologist.

Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with neurosarcoidosis by a multidisciplinary team; and

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- 2 Patient has CNS involvement; and
- 3 Patient has steroid-refractory disease; and
- 4 Either:
 - 4.1 IV cyclophosphamide has been tried; or
 - 4.2 Treatment with IV cyclophosphamide is clinically inappropriate.

Renewal — (neurosarcoidosis) only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months for applications meeting the following criteria:

Either:

- 1 A withdrawal period has been tried and the patient has relapsed; or
- 2 All of the following:
 - 2.1 A withdrawal period has been considered but would not be clinically appropriate; and
 - 2.2 There has been a marked reduction in prednisone dose; and
 - 2.3 Either:
 - 2.3.1 There has been an improvement in MRI appearances; or
 - 2.3.2 Marked improvement in other symptomatology.

Initial application — (plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist.

Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis; and
 - 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab; or
 - 1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
 - 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
 - 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
 - 2.4 The most recent PASI assessment is no more than 1 month old at the time of initiation.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Renewal — (plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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1 Either:

1.1 Both:

- 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
- 1.1.2 Following each prior infliximab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab treatment baseline value; or

1.2 Both:

- 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
- 1.2.2 Either:
 - 1.2.2.1 Following each prior infliximab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
 - 1.2.2.2 Following each prior infliximab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab treatment baseline value; and

2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Initial application — (previous use) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient was being treated with infliximab prior to 1 February 2019; and
- 2 Any of the following:
 - 2.1 Rheumatoid arthritis; or
 - 2.2 Ankylosing spondylitis; or
 - 2.3 Psoriatic arthritis; or
 - 2.4 Severe ocular inflammation; or
 - 2.5 Chronic ocular inflammation; or
 - 2.6 Crohn's disease (adults); or
 - 2.7 Crohn's disease (children); or
 - 2.8 Fistulising Crohn's disease; or
 - 2.9 Severe fulminant ulcerative colitis; or
 - 2.10 Severe ulcerative colitis; or
 - 2.11 Plaque psoriasis; or
 - 2.12 Neurosaroidosis; or
 - 2.13 Severe Behcet's disease.

Initial application — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept and/or secukinumab; or
 - 2.2 Following 3-4 months' initial treatment with adalimumab and/or etanercept and/or secukinumab, the patient did not meet the renewal criteria for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis.

Renewal — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:

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- 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Initial application — (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
 - 2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept; and
- 3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.

Renewal — (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
 - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 3 Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks.

Initial application — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes); and
- 2 Either:
 - 2.1 The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes); or
 - 2.2 The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes); and
- 3 The patient is experiencing significant loss of quality of life.

Notes: Behcet's disease diagnosed according to the International Study Group for Behcet's Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7.

Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.

Renewal — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and

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- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Renewal — (severe fulminant ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (severe ocular inflammation) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe ocular inflammation; or
- 2 Both:
 - 2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
 - 2.2 Any of the following:
 - 2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
 - 2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
 - 2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

Renewal — (severe ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses; or
- 2 Following each 12 month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

Initial application — (ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has histologically confirmed ulcerative colitis; and
- 2 Either:
 - 2.1 Patient is 18 years or older and the Simple Clinical Colitis Activity Index (SCCAI) is greater than or equal to 4; or
 - 2.2 Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (PUCAI) score is greater than or equal to 65; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic

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therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids; and

4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal — (ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and
- 2 Either:
 - 2.1 Patient is 18 years or older and the SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab; or
 - 2.2 Patient is under 18 years and the PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on infliximab; and
- 3 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has pyoderma gangrenosum*; and
- 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
- 3 A maximum of 8 doses.

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

Renewal — (pyoderma gangrenosum) only from a dermatologist or Practitioner on the recommendation of a dermatologist.

Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment; and
- 3 A maximum of 8 doses.

MEPOLIZUMAB – Special Authority see [SA2154 below](#) – Retail pharmacy

Inj 100 mg prefilled pen	1,638.00	1	✓ Nucala
Inj 100 mg vial	1,638.00	1	✓ Nucala

➡SA2154 Special Authority for Subsidy

Initial application — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
- 3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
- 4 Patient has a blood eosinophil count of greater than 0.5×10^9 cells/L in the last 12 months; and
- 5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long acting beta-2 agonist, or budesonide/formoterol as part of the single maintenance and reliever therapy regimen, unless contraindicated or not tolerated; and

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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 Treatment is not to be used in combination with subsidised benralizumab; and

8 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; and

9 Either:

- 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
- 9.2 Both:
 - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
 - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

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.

OBINUTUZUMAB – PCT only – Specialist – Special Authority see [SA2155 below](#)

Inj 25 mg per ml, 40 ml vial.....	5,910.00	1	✓ Gazyva
Inj 1 mg for ECP	6.21	1 mg	✓ Baxter

► **SA2155** Special Authority for Subsidy

Initial application — (chronic lymphocytic leukaemia) only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is obinutuzumab treatment naive; and
- 3 The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min); and
- 4 Patient has adequate neutrophil and platelet counts* unless the cytopenias are a consequence of marrow infiltration by CLL; and
- 5 Patient has good performance status; and
- 6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

Notes: Chronic lymphocytic leukaemia includes small lymphocytic lymphoma. Comorbidity refers only to illness/impairment other than CLL induced illness/impairment in the patient. '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 obinutuzumab is expected to improve symptoms and improve ECOG score to < 2.

* Neutrophil greater than or equal to $1.5 \times 10^9/L$ and platelets greater than or equal to $75 \times 10^9/L$.

Initial application — (follicular / marginal zone lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

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All of the following:

- 1 Either:
 - 1.1 Patient has follicular lymphoma; or
 - 1.2 Patient has marginal zone lymphoma; and
- 2 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen*; and
- 3 Patient has an ECOG performance status of 0-2; and
- 4 Patient has been previously treated with no more than four chemotherapy regimens; and
- 5 Obinutuzumab to be administered at a maximum dose of 1000 mg for a maximum of 6 cycles in combination with chemotherapy*.

Note: * includes unapproved indications

Renewal — (follicular / marginal zone lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 Patient has no evidence of disease progression following obinutuzumab induction therapy; and
- 2 Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years; and
- 3 Obinutuzumab to be discontinued at disease progression.

OMALIZUMAB – Special Authority see [SA1744 below](#) – Retail pharmacy

Inj 150 mg prefilled syringe.....	450.00	1	✓ Xolair
Inj 150 mg vial	450.00	1	✓ Xolair

➡SA1744 Special Authority for Subsidy

Initial application — (severe asthma) only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 6 years or older; and
- 2 Patient has a diagnosis of severe asthma; and
- 3 Past or current evidence of atopy, documented by skin prick testing or RAST; and
- 4 Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
- 5 Proven adherence with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1,600 mcg per day or fluticasone propionate 1,000 mcg per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 mcg bd or eformoterol 12 mcg bd) for at least 12 months, unless contraindicated or not tolerated; and
- 6 Either:
 - 6.1 Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated; or
 - 6.2 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 steroids; and
- 7 Patient has an Asthma Control Test (ACT) score of 10 or less; and
- 8 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 26 weeks after the first dose to assess response to treatment.

Initial application — (severe chronic spontaneous urticaria) only from a clinical immunologist or dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Either:
 - 2.1 Both:

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- 2.1.1 Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above; and
- 2.1.2 Patient has a Dermatology life quality index (DLQI) of 10 or greater; or

- 2.2 Patient has a Urticaria Control Test (UCT) of 8 or less; and

- 3 Any of the following:

- 3.1 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (> 3 mg/kg day) for at least 6 weeks; or
- 3.2 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months; or
- 3.3 Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin; and

- 4 Either:

- 4.1 Treatment to be stopped if inadequate response* following 4 doses; or
- 4.2 Complete response* to 6 doses of omalizumab.

Renewal — (severe asthma) only from a clinical immunologist or respiratory specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline.

Renewal — (severe chronic spontaneous urticaria) only from a clinical immunologist or dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Patient has previously adequately responded* to 6 doses of omalizumab; or
- 2 Both:
 - 2.1 Patient has previously had a complete response* to 6 doses of omalizumab; and
 - 2.2 Patient has relapsed after cessation of omalizumab therapy.

Note: *Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

PALIVIZUMAB – PCT only – Specialist – Special Authority see [SA2143 below](#)

Inj 100 mg per ml, 1 ml vial..... 1,700.00 1 ✓ Synagis

(Synagis Inj 100 mg per ml, 1 ml vial to be delisted 1 January 2024)

► **SA2143 Special Authority for Subsidy**

Initial application — (RSV prophylaxis for the 2022/2023 RSV seasons, in the context of COVID-19) only from a paediatrician. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Infant was born in the last 2 years and has severe lung, airway, neurological or neuromuscular disease that requires ongoing, life-sustaining community ventilation; or
- 2 Both:
 - 2.1 Infant was born in the last 12 months; and
 - 2.2 Any of the following:
 - 2.2.1 Patient was born at less than 28 weeks gestation; or
 - 2.2.2 Both:
 - 2.2.2.1 Patient was born at less than 32 weeks gestation; and
 - 2.2.2.2 Either:
 - 2.2.2.2.1 Patient has chronic lung disease; or
 - 2.2.2.2.2 Patient is Māori or any Pacific ethnicity; or

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2.2.3 Both:

2.2.3.1 Patient has haemodynamically significant heart disease; and

2.2.3.2 Any of the following:

2.2.3.2.1 Patient has unoperated simple congenital heart disease with significant left to right shunt (see note a); or

2.2.3.2.2 Patient has unoperated or surgically palliated complex congenital heart disease; or

2.2.3.2.3 Patient has severe pulmonary hypertension (see note b); or

2.2.3.2.4 Patient has moderate or severe LV failure (see note c).

Notes:

- Patient requires/will require heart failure medication, and/or patient has significant pulmonary hypertension, and/or patient will require surgical palliation/definitive repair within the next 3 months.
- Mean pulmonary artery pressure more than 25 mmHg.
- LV Ejection Fraction less than 40%.

Renewal — (RSV prophylaxis for the 2022/2023 RSV seasons, in the context of COVID-19) only from a paediatrician.

Approvals valid for 6 months where patient still meets initial criteria.

PERTUZUMAB – PCT only – Specialist – Special Authority see SA1606 below

Inj 30 mg per ml, 14 ml vial.....	3,927.00	1	✓ Perjeta
Inj 420 mg for ECP	3,927.00	420 mg OP	✓ Baxter

►SA1606 Special Authority for Subsidy

Initial application — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- Either:
 - Patient is chemotherapy treatment naïve; or
 - Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
- The patient has good performance status (ECOG grade 0-1); and
- Pertuzumab to be administered in combination with trastuzumab; and
- Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
- Pertuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab.

RITUXIMAB (MABTHERA) – PCT only – Specialist – Special Authority see SA1976 below

Inj 100 mg per 10 ml vial	1,075.50	2	✓ Mabthera
Inj 500 mg per 50 ml vial	2,688.30	1	✓ Mabthera
Inj 1 mg for ECP	5.64	1 mg	✓ Baxter (Mabthera)

►SA1976 Special Authority for Subsidy

Initial application — (rheumatoid arthritis - TNF inhibitors contraindicated) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

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

Initial application — (rheumatoid arthritis - prior TNF inhibitor use) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

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

Renewal — (rheumatoid arthritis - re-treatment in 'partial responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:

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- 1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
- 3 Either:
 - 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
 - 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Renewal — (rheumatoid arthritis - re-treatment in 'responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
- 3 Either:
 - 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
 - 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

RITUXIMAB (RIXIMYO) – PCT only – Specialist – Special Authority see [SA2114 below](#)

Inj 100 mg per 10 ml vial	275.33	2	✓ Riximyo
Inj 500 mg per 50 ml vial	688.20	1	✓ Riximyo
Inj 1 mg for ECP	1.38	1 mg	✓ Baxter (Riximyo)

►SA2114 Special Authority for Subsidy

Initial application — (ABO-incompatible organ transplant) from any relevant practitioner. Approvals valid without further renewal unless notified where patient is to undergo an ABO-incompatible solid organ transplant*.

Note: Indications marked with * are unapproved indications.

Initial application — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 8 weeks for applications meeting the following criteria:

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

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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.

Renewal — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 8 weeks for applications meeting the following criteria:

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.

Initial application — (Antibody-mediated organ transplant rejection) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has been diagnosed with antibody-mediated organ transplant rejection*.

Note: Indications marked with * are unapproved indications.

Initial application — (Chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

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 naive; or

2.2 Either:

2.2.1 The patient is chemotherapy treatment naive; or

2.2.2 Both:

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

2.2.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; 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 The patient has good performance status; and

4 Either:

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

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

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

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

Renewal — (Chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

1 Either:

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

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

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

Initial application — (Neuromyelitis Optica Spectrum Disorder(NMOSD)) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m² administered weekly for four weeks; and
- 2 Either:
 - 2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or
 - 2.2 All of the following:
 - 2.2.1 The patient has experienced a breakthrough attack of NMOSD; and
 - 2.2.2 The patient is receiving treatment with mycophenolate; and
 - 2.2.3 The patient is receiving treatment with corticosteroids.

Renewal — (Neuromyelitis Optica Spectrum Disorder) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m² administered weekly for four weeks; and
- 2 The patient has responded to the most recent course of rituximab; and
- 3 The patient has not received rituximab in the previous 6 months.

Initial application — (Post-transplant) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has B-cell post-transplant lymphoproliferative disorder*; and
- 2 To be used for a maximum of 8 treatment cycles.

Note: Indications marked with * are unapproved indications.

Renewal — (Post-transplant) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has B-cell post-transplant lymphoproliferative disorder*; and
- 3 To be used for no more than 6 treatment cycles.

Note: Indications marked with * are unapproved indications.

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Initial application — (Severe Refractory Myasthenia Gravis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 One of the following dose regimens is to be used: 375 mg/m² of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- 2 Either:
 - 2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or
 - 2.2 Both:
 - 2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
 - 2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Renewal — (Severe Refractory Myasthenia Gravis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

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

Initial application — (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria:

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 * are unapproved indications.

Renewal — (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria:

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.

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

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Note: Indications marked with * are unapproved indications.

Initial application — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria:

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 * are unapproved indications.

Renewal — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient who was previously treated with rituximab for nephrotic syndrome*;
- 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 * are unapproved indications.

Initial application — (aggressive CD20 positive NHL) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 The patient has treatment naive aggressive CD20 positive NHL; and
 - 1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
 - 1.3 To be used for a maximum of 8 treatment cycles; or
- 2 Both:
 - 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
 - 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

Renewal — (aggressive CD20 positive NHL) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
- 3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
- 4 To be used for a maximum of 4 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

Initial application — (haemophilia with inhibitors) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

- 1 Patient has mild congenital haemophilia complicated by inhibitors; or
- 2 Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy; or
- 3 Patient has acquired haemophilia.

Renewal — (haemophilia with inhibitors) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:

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All of the following:

- 1 Patient was previously treated with rituximab for haemophilia with inhibitors; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment.

Initial application — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 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.

Renewal — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

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.

Initial application — (indolent, low-grade lymphomas or hairy cell leukaemia*) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
 - 1.2 To be used for a maximum of 6 treatment cycles; or
- 2 Both:
 - 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy; and
 - 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Renewal — (indolent, low-grade lymphomas or hairy cell leukaemia*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and

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- 2 The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
- 3 To be used for no more than 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Initial application — (pure red cell aplasia (PRCA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient has autoimmune pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder.

Note: Indications marked with * are unapproved indications.

Renewal — (pure red cell aplasia (PRCA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient was previously treated with rituximab for pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months.

Note: Indications marked with * are unapproved indications.

Initial application — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 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.

Renewal — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

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.

Initial application — (thrombotic thrombocytopenic purpura (TTP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

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.

Renewal — (thrombotic thrombocytopenic purpura (TTP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

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

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- 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.

Initial application — (treatment refractory systemic lupus erythematosus (SLE)) only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 7 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe, immediately life- or organ-threatening SLE*; and
- 2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and
- 3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and
- 4 Maximum of four 1000 mg infusions of rituximab.

Note: Indications marked with * are unapproved indications.

Renewal — (treatment refractory systemic lupus erythematosus (SLE)) only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient's SLE* achieved at least a partial response to the previous round of prior rituximab treatment; and
- 2 The disease has subsequently relapsed; and
- 3 Maximum of two 1000 mg infusions of rituximab.

Note: Indications marked with * are unapproved indications.

Initial application — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 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.

Renewal — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

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.

Initial application — (severe antisynthetase syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed antisynthetase syndrome; and
- 2 Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and

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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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3 Either:

- 3.1 Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not been effective at controlling active disease; or
- 3.2 Rapid treatment is required due to life threatening complications; and

4 Maximum of four 1,000mg infusions of rituximab.

Renewal — (severe antisynthetase syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function; and
- 2 The patient has not received rituximab in the previous 6 months; and
- 3 Maximum of two cycles of $2 \times 1,000\text{mg}$ infusions of rituximab given two weeks apart.

Initial application — (graft versus host disease) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 Patient has refractory graft versus host disease following transplant; and
- 2 Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not been effective at controlling active disease; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.

Initial application — (severe chronic inflammatory demyelinating polyneuropathy) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD); and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
 - 2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
 - 2.2 Rapid treatment is required due to life threatening complications; and
- 3 One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Renewal — (severe chronic inflammatory demyelinating polyneuropathy) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function compared to baseline; and
- 2 The patient has not received rituximab in the previous 6 months; and
- 3 One of the following dose regimens is to be used: 375 mg/m^2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Initial application — (anti-NMDA receptor autoimmune encephalitis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe anti-NMDA receptor autoimmune encephalitis; and
- 2 Either:
 - 2.1 Both:

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- 2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
- 2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
- 2.2 Rapid treatment is required due to life threatening complications; and

- 3 One of the following dose regimens is to be used: 375 mg/m² of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Renewal — (anti-NMDA receptor autoimmune encephalitis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function; and
- 2 The patient has not received rituximab in the previous 6 months; and
- 3 The patient has experienced a relapse and now requires further treatment; and
- 4 One of the following dose regimens is to be used: 375 mg/m² of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Initial application — (CD20+ low grade or follicular B-cell NHL) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has CD20+ low grade or follicular B-cell NHL with relapsed disease following prior chemotherapy; and
 - 1.2 To be used for a maximum of 6 treatment cycles; or
- 2 Both:
 - 2.1 The patient has CD20+ low grade or follicular B-cell NHL requiring first-line systemic chemotherapy; and
 - 2.2 To be used for a maximum of 6 treatment cycles.

Renewal — (CD20+ low grade or follicular B-cell NHL) from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria:

Both:

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

Initial application — (Membranous nephropathy) only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Patient has biopsy-proven primary/idiopathic membranous nephropathy*; or
 - 1.2 Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m²; and
- 2 Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note); and
- 3 The total rituximab dose would not exceed the equivalent of 375mg/m² of body surface area per week for a total of 4 weeks.

Renewal — (Membranous nephropathy) only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient was previously treated with rituximab for membranous nephropathy*; and
- 2 Either:

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

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- 2.1 Treatment with rituximab was previously successful, but the condition has relapsed, and the patient now requires repeat treatment; or
- 2.2 Patient achieved partial response to treatment and requires repeat treatment (see Note); and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Notes:

- a) Indications marked with * are unapproved indications.
- b) High risk of progression to end-stage kidney disease defined as > 5g/day proteinuria.
- c) Conservative measures include renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents unless contraindicated or the patient has experienced intolerable side effects.
- d) Partial response defined as a reduction of proteinuria of at least 50% from baseline, and between 0.3 grams and 3.5 grams per 24 hours.

Initial application — (B-cell acute lymphoblastic leukaemia/lymphoma*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient has newly diagnosed B-cell acute lymphoblastic leukaemia/lymphoma*; and
- 2 Treatment must be in combination with an intensive chemotherapy protocol with curative intent; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/m² per dose for a maximum of 18 doses.

Note: Indications marked with * are unapproved indications.

Initial application — (desensitisation prior to transplant) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient requires desensitisation prior to mismatched allogeneic stem cell transplant*; and
- 2 Patient would receive no more than two doses at 375 mg/m² of body-surface area.

Note: Indications marked with * are unapproved indications.

Initial application — (pemphigus*) only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 Patient has severe rapidly progressive pemphigus; and
 - 1.2 Is used in combination with systemic corticosteroids (20 mg/day); and
 - 1.3 Any of the following:
 - 1.3.1 Skin involvement is at least 5% body surface area; or
 - 1.3.2 Significant mucosal involvement (10 or more mucosal erosions) or diffuse gingivitis or confluent large erosions; or
 - 1.3.3 Involvement of two or more mucosal sites; or
- 2 Both:
 - 2.1 Patient has pemphigus; and
 - 2.2 Patient has not experienced adequate clinical benefit from systemic corticosteroids (20 mg/day) in combination with a steroid sparing agent, unless contraindicated.

Note: Indications marked with * are unapproved indications.

Renewal — (pemphigus*) only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has experienced adequate clinical benefit from rituximab treatment, with improvement in symptoms and healing of

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skin ulceration and reduction in corticosteroid requirement; and

2 Patient has not received rituximab in the previous 6 months.

Note: Indications marked with * are unapproved indications.

SECUKINUMAB – Special Authority see [SA2084 below](#) – Retail pharmacy

Inj 150 mg per ml, 1 ml prefilled syringe.....	799.50	1	✓ Cosentyx
	1,599.00	2	✓ Cosentyx

►[SA2084](#) Special Authority for Subsidy

Initial application — (severe chronic plaque psoriasis – second-line biologic) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a Health NZ Hospital, for severe chronic plaque psoriasis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
 - 2.2 The patient has received insufficient benefit from adalimumab, etanercept or infliximab; and
- 3 A Psoriasis Area and Severity Index (PASI) assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

Initial application — (severe chronic plaque psoriasis – first-line biologic) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
- 2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
- 3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

Note: A treatment course is defined as a minimum of 12 weeks of treatment. "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom sub scores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Renewal — (severe chronic plaque psoriasis – first and second-line biologic) only from a dermatologist or medical practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

- Both:
- 1 Either:
 - 1.1 Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab; or

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

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- 1.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and

- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

Initial application — (ankylosing spondylitis – second-line biologic) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
 - 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

Renewal — (ankylosing spondylitis – second-line biologic) only from a rheumatologist or medical practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Following 12 weeks initial treatment of secukinumab treatment, BASDAI has improved by 4 or more points from pre-secukinumab baseline on a 10 point scale, or by 50%, whichever is less; and
- 2 Physician considers that the patient has benefitted from treatment and that continued treatment is appropriate; and
- 3 Secukinumab to be administered at doses no greater than 150 mg monthly.

Initial application — (psoriatic arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis; and
 - 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
 - 1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or infliximab to meet the renewal criteria for adalimumab, etanercept or infliximab for psoriatic arthritis; or
- 2 All of the following:
 - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
 - 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
 - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
 - 2.4 Either:
 - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
 - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
 - 2.5 Any of the following:
 - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
 - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

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Both:

1 Either:

- 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior secukinumab treatment in the opinion of the treating physician; and

2 Secukinumab to be administered at doses no greater than 300 mg monthly.

SILTUXIMAB – Special Authority see [SA1596 below](#) – Retail pharmacy

Note: Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Inj 100 mg vial	770.57	1	✓ Sylvant
Inj 400 mg vial	3,082.33	1	✓ Sylvant

➤ **SA1596** Special Authority for Subsidy

Initial application only from a haematologist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Renewal only from a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status.

TIXAGEVIMAB WITH CILGAVIMAB – [Xpharm] – Subsidy by endorsement

- a) No patient co-payment payable
- b) Treatment is funded only if patient meets access criteria for tixagevimab with cilgavimab (as per <https://pharmac.govt.nz/Evusheld>) and has been endorsed accordingly by the prescriber. The supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability.

Inj 100 mg per ml, 1.5 ml vial with cilgavimab 100 mg per ml, 1.5 ml vial.....	0.00	1	✓ Evusheld
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TOCILIZUMAB – PCT only – Special Authority see [SA2100 below](#)

Inj 20 mg per ml, 4 ml vial.....	220.00	1	✓ Actemra
			✓ Actemra S29 ^{S29}
	880.00	4	✓ RoActemra S29 ^{S29}
Inj 20 mg per ml, 10 ml vial.....	550.00	1	✓ RoActemra S29 ^{S29}
			✓ Actemra
			✓ Actemra S29 ^{S29}
			✓ RoActemra S29 ^{S29}
Inj 20 mg per ml, 20 ml vial.....	1,100.00	1	✓ Actemra
			✓ Actemra S29 ^{S29}
			✓ RoActemra S29 ^{S29}
	4,400.00	4	✓ RoActemra S29 ^{S29}
Inj 1 mg for ECP	2.85	1 mg	✓ Baxter

➤ **SA2100** Special Authority for Subsidy

Initial application — (cytokine release syndrome) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

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▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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1 All of the following:

- 1.1 The patient is enrolled in the Children's Oncology Group AALL1731 trial; and
- 1.2 The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia; and
- 1.3 Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses (if less than 30kg, maximum of 12 mg/kg); or

2 All of the following:

- 2.1 The patient is enrolled in the Malaghan Institute of Medical Research Phase I ENABLE trial; and
- 2.2 The patient has developed CRS or CAR T-Cell Related Encephalopathy Syndrome (CRES) associated with the administration of CAR T-cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma; and
- 2.3 Tocilizumab is to be administered according to the consensus guidelines for CRS and CRES for CAR T-cell therapy (Neelapu et al. Nat Rev Clin Oncol 2018;15:47-62) at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

Initial application — (previous use) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient was being treated with tocilizumab prior to 1 February 2019; and

2 Any of the following:

- 2.1 rheumatoid arthritis; or
- 2.2 systemic juvenile idiopathic arthritis; or
- 2.3 adult-onset Still's disease; or
- 2.4 polyarticular juvenile idiopathic arthritis; or
- 2.5 idiopathic multicentric Castleman's disease.

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
 - 2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
- 3 Either:
 - 3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
 - 3.2 Both:
 - 3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital; and
 - 3.2.2 Either:
 - 3.2.2.1 The patient has experienced intolerable side effects from rituximab; or
 - 3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Initial application — (Rheumatoid Arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
- 2 Tocilizumab is to be used as monotherapy; and
- 3 Either:
 - 3.1 Treatment with methotrexate is contraindicated; or

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- 3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
- 4 Either:
 - 4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent; or
 - 4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and
- 5 Either:
 - 5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints; or
 - 5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 6 Either:
 - 6.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 6.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initial application — (systemic juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient diagnosed with systemic juvenile idiopathic arthritis; and
- 2 Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotrexate; non-steroidal anti-inflammatory drugs (NSAIDs); and systemic corticosteroids.

Initial application — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Either:
 - 1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD); or
 - 1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
 - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD; or
- 2 All of the following:
 - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
 - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate; and
 - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initial application — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
 - 1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or

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2 All of the following:

- 2.1 Treatment with a tumour necrosis factor alpha inhibitor is contraindicated; and
- 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
- 2.3 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.4 Any of the following:

- 2.4.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
- 2.4.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
- 2.4.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Initial application — (idiopathic multicentric Castleman's disease) only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Tocilizumab to be administered at doses no greater than 8 mg/kg IV every 3-4 weeks.

Initial application — (moderate to severe COVID-19*) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed (or probable) COVID-19; and
- 2 Oxygen saturation of < 92% on room air, or requiring supplemental oxygen; and
- 3 Patient is receiving adjunct systemic corticosteroids, or systemic corticosteroids are contraindicated; and
- 4 Tocilizumab is to be administered at doses no greater than 8mg/kg IV for a maximum of one dose; and
- 5 Tocilizumab is not to be administered in combination with baricitinib.

Note: Indications marked with * are unapproved indications.

Renewal — (Rheumatoid Arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

Renewal — (systemic juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Following up to 6 months' initial treatment, the patient has achieved at least an American College of Rheumatology paediatric 30% improvement criteria (ACR Pedi 30) response from baseline; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has a sustained improvement in inflammatory markers and functional status.

Renewal — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

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2 Either:

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

Renewal — (idiopathic multicentric Castleman's disease) only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status.

TRASTUZUMAB – PCT only – Specialist – Special Authority see SA1632 below

Inj 150 mg vial	1,350.00	1	✓ Herceptin
Inj 440 mg vial	3,875.00	1	✓ Herceptin
Inj 1 mg for ECP	9.36	1 mg	✓ Baxter

►SA1632 Special Authority for Subsidy

Initial application — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Either:
 - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
 - 2.2 Both:
 - 2.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
 - 2.2.2 The cancer did not progress whilst on lapatinib; and
- 3 Either:
 - 3.1 Trastuzumab will not be given in combination with pertuzumab; or
 - 3.2 All of the following:
 - 3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
 - 3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
 - 3.2.3 The patient has good performance status (ECOG grade 0-1); and
- 4 Trastuzumab not to be given in combination with lapatinib; and
- 5 Trastuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 3 Trastuzumab not to be given in combination with lapatinib; and
- 4 Trastuzumab to be discontinued at disease progression.

Initial application — (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 15 months for applications meeting the following criteria:

All of the following:

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

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- 2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
- 3 Any of the following:
 - 3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
 - 3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or
 - 3.5 Other treatment regimen, in association with adjuvant chemotherapy, is planned.

Renewal — (early breast cancer*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
- 3 Any of the following:
 - 3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
 - 3.2 Both:
 - 3.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
 - 3.2.2 The cancer did not progress whilst on lapatinib; or
 - 3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 4 Either:
 - 4.1 Trastuzumab will not be given in combination with pertuzumab; or
 - 4.2 All of the following:
 - 4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
 - 4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
 - 4.2.3 The patient has good performance status (ECOG grade 0-1); and
- 5 Trastuzumab not to be given in combination with lapatinib; and
- 6 Trastuzumab to be discontinued at disease progression.

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

TRASTUZUMAB EMTANSINE – PCT only – Specialist – Special Authority see [SA2144](#) below

Inj 100 mg vial	2,320.00	1	✓ Kadcyła
Inj 160 mg vial	3,712.00	1	✓ Kadcyła
Inj 1 mg for ECP	24.52	1 mg	✓ Baxter

►SA2144 Special Authority for Subsidy

Initial application — (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has early breast cancer expressing HER2 IHC3+ or ISH+; and
- 2 Documentation of pathological invasive residual disease in the breast and/or auxiliary lymph nodes following completion of surgery; and
- 3 Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery; and
- 4 Disease has not progressed during neoadjuvant therapy; and
- 5 Patient has left ventricular ejection fraction of 45% or greater; and

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- 6 Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery; and
- 7 Trastuzumab emtansine to be discontinued at disease progression; and
- 8 Total adjuvant treatment duration must not exceed 42 weeks (14 cycles).

Initial application — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

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 Patient has not received prior funded trastuzumab emtansine treatment; and
- 7 Treatment to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

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

Programmed Cell Death-1 (PD-1) Inhibitors

DURVALUMAB – PCT only – Specialist – Special Authority see [SA2147](#) below

Inj 50 mg per ml, 10 ml vial.....	4,700.00	1	✓ Imfinzi
Inj 50 mg per ml, 2.4 ml vial.....	1,128.00	1	✓ Imfinzi
Inj 1 mg for ECP	9.59	1 mg	✓ Baxter

➤SA2147 Special Authority for Subsidy

Initial application — (Non-small cell lung cancer) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 Patient is currently on treatment with durvalumab and met all remaining criteria (criterion 2) below prior to commencing treatment; or
- 2 All of the following:
 - 2.1 Patient has histologically or cytologically documented stage III, locally advanced, unresectable non-small cell lung cancer (NSCLC); and
 - 2.2 Patient has received two or more cycles of platinum-based chemotherapy concurrently with definitive radiation therapy; and
 - 2.3 Patient has no disease progression following the second or subsequent cycle of platinum-based chemotherapy with definitive radiation therapy treatment; and
 - 2.4 Patient has a ECOG performance status of 0 or 1; and
 - 2.5 Patient has completed last radiation dose within 8 weeks of starting treatment with durvalumab; and
 - 2.6 Patient must not have received prior PD-1 or PD-L1 inhibitor therapy for this condition; and

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2.7 Either:

- 2.7.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
- 2.7.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and

2.8 Treatment with durvalumab to cease upon signs of disease progression.

Renewal — (Non-small cell lung cancer) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The treatment remains clinically appropriate and the patient is benefitting from treatment; and
- 2 Either:
 - 2.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
 - 2.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
- 3 Treatment with durvalumab to cease upon signs of disease progression; and
- 4 Total continuous treatment duration must not exceed 12 months.

NIVOLUMAB – PCT only – Specialist – Special Authority see [SA2120 below](#)

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
Inj 1 mg for ECP	27.62	1 mg	✓ Baxter

►SA2120 Special Authority for Subsidy

Initial application only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

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 Baseline measurement of overall tumour burden is documented (see Note); and
- 6 Documentation confirming that the patient has been informed and acknowledges that funded treatment with nivolumab will not be continued if their disease progresses.

Renewal only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

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 Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and
 - 1.3 No evidence of progressive disease according to RECIST criteria (see Note); and
 - 1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
- 2 All of the following:
 - 2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease

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- progression; and
- 2.2 Patient has signs of disease progression; and
- 2.3 Disease has not progressed during previous treatment with nivolumab.

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.

PEMBROLIZUMAB – PCT only – Specialist – Special Authority see [SA2121](#) below

Inj 25 mg per ml, 4 ml vial.....	4,680.00	1	✓ Keytruda
Inj 1 mg for ECP	49.14	1 mg	✓ Baxter

►SA2121 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

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 Baseline measurement of overall tumour burden is documented (see Note); and
- 6 Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses.

Renewal — (unresectable or metastatic melanoma) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

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

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- 1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
- 1.2 Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and
- 1.3 No evidence of progressive disease according to RECIST criteria (see Note); and
- 1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
- 2 All of the following:
 - 2.1 Patient has previously discontinued treatment with 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.

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.

Other Immunosuppressants

CICLOSPORIN

Cap 25 mg	44.63	50	✓ Neoral
Cap 50 mg	88.91	50	✓ Neoral
Cap 100 mg	177.81	50	✓ Neoral
Oral liq 100 mg per ml	198.13	50 ml OP	✓ Neoral

EVEROLIMUS – Special Authority see [SA2008 below](#) – Retail pharmacy

Wastage claimable			
Tab 10 mg	6,512.29	30	✓ Afinitor
Tab 5 mg	4,555.76	30	✓ Afinitor

► [SA2008](#) Special Authority for Subsidy

Initial application only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient has tuberous sclerosis; and
- 2 Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

Renewal only from a neurologist or oncologist. Approvals valid for 12 months for applications meeting the following criteria:

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All of the following:

- 1 Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Everolimus to be discontinued at progression of SEGAs.

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.

SIROLIMUS – Special Authority see [SA2005 below](#) – Retail pharmacy

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

►SA2005 Special Authority for Subsidy

Initial application from any medical practitioner. Approvals valid without further renewal unless notified where the drug is to be used for rescue therapy for an organ transplant recipient.

Notes: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following:

- GFR< 30 ml/min; or
- Rapidly progressive transplant vasculopathy; or
- Rapidly progressive obstructive bronchiolitis; or
- HUS or TTP; or
- Leukoencephalopathy; or
- Significant malignant disease

Initial application — (severe non-malignant lymphovascular malformations*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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

Renewal — (severe non-malignant lymphovascular malformations*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Patient's disease has had either a complete response or a partial response to treatment, or patient has stable disease according to RECIST version 1.1 (see Note); or
 - 1.2 Patient's disease has stabilised or responded clinically and disease response to treatment has been clearly documents in patient notes; and
- 2 No evidence of progressive disease; and
- 3 The treatment remains clinically appropriate and the patient is benefitting from the treatment.

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

Indications marked with * are unapproved indications

Initial application — (renal angiomyolipoma(s) associated with tuberous sclerosis complex*) only from a nephrologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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- 1 Patient has tuberous sclerosis complex*; and
- 2 Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth.

Renewal — (renal angiomyolipoma(s) associated with tuberous sclerosis complex*) from any relevant practitioner.

Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Documented evidence of renal angiomyolipoma reduction or stability by magnetic resonance imaging (MRI) or ultrasound; and
- 2 Demonstrated stabilisation or improvement in renal function; and
- 3 The patient has not experienced angiomyolipoma haemorrhage or significant adverse effects to sirolimus treatment; and
- 4 The treatment remains appropriate and the patient is benefiting from treatment.

Note: Indications marked with * are unapproved indications

Initial application — (refractory seizures associated with tuberous sclerosis complex*) only from a neurologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has epilepsy with a background of documented tuberous sclerosis complex; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Vigabatrin has been trialled and has not adequately controlled seizures; and
 - 2.1.2 Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least two of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note); or
 - 2.2 Both:
 - 2.2.1 Vigabatrin is contraindicated; and
 - 2.2.2 Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least three of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note); and
- 3 Seizures have a significant impact on quality of life; and
- 4 Patient has been assessed and surgery is considered inappropriate for this patient, or the patient has been assessed and would benefit from mTOR inhibitor treatment prior to surgery.

Note: "Optimal treatment" is defined as treatment, which is indicated and clinically appropriate for the patient, given in adequate doses for the patients age, weight and other features affecting the pharmacokinetics of the drug, with good evidence of adherence. Women of childbearing age are not required to have a trial of sodium valproate.

Renewal — (refractory seizures associated with tuberous sclerosis complex*) only from a neurologist. Approvals valid for 12 months where demonstrated significant and sustained improvement in seizure rate (e.g. 50% reduction in seizure frequency) or severity and/or patient quality of life compared with baseline prior to starting sirolimus treatment.

Note: Indications marked with * are unapproved indications

TACROLIMUS – Special Authority see [SA1745 below](#) – Retail pharmacy

Cap 0.5 mg.....	49.60	100	✓ Tacrolimus Sandoz
Cap 0.75 mg.....	99.30	100	✓ Tacrolimus Sandoz
Cap 1 mg.....	84.30	100	✓ Tacrolimus Sandoz
Cap 5 mg.....	248.20	50	✓ Tacrolimus Sandoz

► [SA1745](#) Special Authority for Subsidy

Initial application — (organ transplant) only from a relevant specialist. Approvals valid without further renewal unless notified where the patient is an organ transplant recipient.

Note: Subsidy applies for either primary or rescue therapy.

Initial application — (non-transplant indications*) only from a relevant specialist. Approvals valid without further renewal

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

unless notified for applications meeting the following criteria:

Both:

- 1 Patient requires long-term systemic immunosuppression; and
- 2 Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response.

Note: Indications marked with * are unapproved indications

JAK inhibitors

UPADACITINIB – Special Authority see [SA2079 below](#) – Retail pharmacy

Tab 15 mg	1,271.00	28	✓ RINVOQ
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➔SA2079 Special Authority for Subsidy

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
 - 2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
- 3 Either:
 - 3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
 - 3.2 Both:
 - 3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital; and
 - 3.2.2 Either:
 - 3.2.2.1 The patient has experienced intolerable side effects from rituximab; or
 - 3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Renewal — (Rheumatoid Arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Antiallergy Preparations

Allergic Emergencies

ICATIBANT – Special Authority see [SA1558 below](#) – Retail pharmacy

Inj 10 mg per ml, 3 ml prefilled syringe	2,668.00	1	✓ Firazyr
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► **SA1558** **Special Authority for Subsidy**

Initial application only from a clinical immunologist or relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency; and
- 2 The patient has undergone product training and has agreed upon an action plan for self-administration.

Renewal from any relevant practitioner. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Allergy Desensitisation

► **SA1367** **Special Authority for Subsidy**

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

Renewal only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

BEE VENOM ALLERGY TREATMENT – Special Authority see [SA1367 above](#) – Retail pharmacy

Initiation kit - 5 vials freeze dried venom with diluent	305.00	1 OP	✓ VENOX <small>\$29</small>
Maintenance kit - 1 vial freeze dried venom with diluent	305.00	1 OP	✓ VENOX <small>\$29</small>
Maintenance kit - 6 vials 120 mcg freeze dried venom, with diluent	285.00	1 OP	✓ Venomil <small>\$29</small>
Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent 9 ml, 3 diluent 1.8 ml	305.00	1 OP	✓ Albey
Treatment kit - 1 vial 550 mcg freeze dried venom, with diluent	305.00	1 OP	✓ Hymenoptera <small>\$29</small>

WASP VENOM ALLERGY TREATMENT – Special Authority see [SA1367 above](#) – Retail pharmacy

Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze dried polister venom, 1 diluent 9 ml, 1 diluent 1.8 ml	305.00	1 OP	✓ Albey
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze dried venom, with diluent	305.00	1 OP	✓ Hymenoptera <small>\$29</small>
Treatment kit (Paper wasp venom) - 6 vials 120 mcg freeze dried venom, with diluent	305.00	1 OP	✓ Venomil <small>\$29</small>
Treatment kit (Yellow Jacket venom) - 1 vial 550 mcg freeze dried venom, with diluent	305.00	1 OP	✓ Hymenoptera <small>\$29</small>
Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze dried vespula venom, 1 diluent 9 ml, 1 diluent 1.8 ml	305.00	1 OP	✓ Albey
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze dried venom, with diluent	305.00	1 OP	✓ Venomil <small>\$29</small>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Antihistamines				
CETIRIZINE HYDROCHLORIDE				
* Tab 10 mg	1.12	100	✓	Zista
* Oral liq 1 mg per ml	2.84	200 ml	✓	Histaclear
CHLORPHENIRAMINE MALEATE				
* Oral liq 2 mg per 5 ml	9.37	500 ml	✓	Histafen
DEXTROCHLORPHENIRAMINE MALEATE				
* Tab 2 mg	2.02	40		
	(8.40)			Polaramine
	1.01	20		
	(5.99)			Polaramine
* Oral liq 2 mg per 5 ml	1.77	100 ml		
	(10.29)			Polaramine
FEXOFENADINE HYDROCHLORIDE				
* Tab 60 mg	4.34	20		
	(8.23)			Telfast
* Tab 120 mg	4.74	10		
	(8.23)			Telfast
	14.22	30		
	(26.44)			Telfast
LORATADINE				
* Tab 10 mg	1.78	100	✓	Lorafix
* Oral liq 1 mg per ml	1.43	100 ml	✓	Haylor syrup
PROMETHAZINE HYDROCHLORIDE				
* Tab 10 mg	1.39	50	✓	Allersoothe
* Tab 25 mg	1.58	50	✓	Allersoothe
* Oral liq 1 mg per 1 ml	3.39	100 ml	✓	Allersoothe
* Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	17.87	5	✓	Hospira
Inhaled Corticosteroids				
BECLOMETHASONE DIPROPIONATE				
Aerosol inhaler, 50 mcg per dose	14.01	200 dose OP	✓	Qvar
Aerosol inhaler, 50 mcg per dose CFC-free	8.54	200 dose OP	✓	Beclazone 50
Aerosol inhaler, 100 mcg per dose	17.52	200 dose OP	✓	Qvar
Aerosol inhaler, 100 mcg per dose CFC-free	12.50	200 dose OP	✓	Beclazone 100
Aerosol inhaler, 250 mcg per dose CFC-free	22.67	200 dose OP	✓	Beclazone 250
BUDESONIDE				
Powder for inhalation, 100 mcg per dose	17.00	200 dose OP	✓	Pulmicort Turbuhaler
Powder for inhalation, 200 mcg per dose	19.00	200 dose OP	✓	Pulmicort Turbuhaler
Powder for inhalation, 400 mcg per dose	32.00	200 dose OP	✓	Pulmicort Turbuhaler

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLUTICASONE				
Aerosol inhaler, 50 mcg per dose.....	7.19	120 dose OP	✓	Flixotide
Powder for inhalation, 50 mcg per dose.....	7.50	60 dose OP	✓	Flixotide Accuhaler
Powder for inhalation, 100 mcg per dose.....	7.50	60 dose OP	✓	Flixotide Accuhaler
Aerosol inhaler, 125 mcg per dose.....	13.60	120 dose OP	✓	Flixotide
Aerosol inhaler, 250 mcg per dose.....	24.62	120 dose OP	✓	Flixotide
Powder for inhalation, 250 mcg per dose.....	13.60	60 dose OP	✓	Flixotide Accuhaler

Inhaled Long-acting Beta-adrenoceptor Agonists

EFORMOTEROL FUMARATE

Powder for inhalation, 12 mcg per dose, and monodose device.....	20.64 (35.80)	60 dose		Foradil
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(Foradil Powder for inhalation, 12 mcg per dose, and monodose device to be delisted 1 July 2023)

EFORMOTEROL FUMARATE DIHYDRATE

Powder for inhalation 4.5 mcg per dose, breath activated (equivalent to eformoterol fumarate 6 mcg metered dose).....	10.32 (16.90)	60 dose OP		Oxis Turbuhaler
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INDACATEROL

Powder for inhalation 150 mcg.....	61.00	30 dose OP	✓	Onbrez Breezhaler
Powder for inhalation 300 mcg.....	61.00	30 dose OP	✓	Onbrez Breezhaler

SALMETEROL

Aerosol inhaler CFC-free, 25 mcg per dose.....	26.25	120 dose OP	✓	Serevent
Powder for inhalation, 50 mcg per dose, breath activated.....	26.25	60 dose OP	✓	Serevent Accuhaler

Inhaled Corticosteroids with Long-Acting Beta-Adrenoceptor Agonists

BUDESONIDE WITH EFORMOTEROL

Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide with 6 mcg eformoterol fumarate metered dose).....	41.50	120 dose OP	✓	DuoResp Spiromax
Powder for inhalation 320 mcg with 9 mcg eformoterol fumarate per dose (equivalent to 400 mcg budesonide with 12 mcg eformoterol fumarate metered dose) – No more than 2 dose per day.....	82.50	120 dose OP	✓	DuoResp Spiromax
Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg.....	18.23	120 dose OP	✓	Vannair
Powder for inhalation 100 mcg with eformoterol fumarate 6 mcg.....	33.74	120 dose OP	✓	Symbicort Turbuhaler 100/6
Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg.....	21.40	120 dose OP	✓	Vannair
Powder for inhalation 200 mcg with eformoterol fumarate 6 mcg.....	33.74	120 dose OP	✓	Symbicort Turbuhaler 200/6
Powder for inhalation 400 mcg with eformoterol fumarate 12 mcg – No more than 2 dose per day.....	33.74	60 dose OP	✓	Symbicort Turbuhaler 400/12

FLUTICASONE FUROATE WITH VILANTEROL

Powder for inhalation 100 mcg with vilanterol 25 mcg.....	44.08	30 dose OP	✓	Breo Ellipta
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLUTICASONE WITH SALMETEROL				
Aerosol inhaler 50 mcg with salmeterol 25 mcg	25.79	120 dose OP	✓	Seretide
Aerosol inhaler 125 mcg with salmeterol 25 mcg	32.60	120 dose OP	✓	Seretide
Powder for inhalation 100 mcg with salmeterol 50 mcg – No more than 2 dose per day	33.74	60 dose OP	✓	Seretide Accuhaler
Powder for inhalation 250 mcg with salmeterol 50 mcg – No more than 2 dose per day	44.08	60 dose OP	✓	Seretide Accuhaler

Beta-Adrenoceptor Agonists

SALBUTAMOL				
Oral liq 400 mcg per ml	40.00	150 ml	✓	Ventolin
Infusion 1 mg per ml, 5 ml	118.38	10	✓	Ventolin
Inj 500 mcg per ml, 1 ml – Up to 5 inj available on a PSO	53.00	5	✓	Ventolin

Inhaled Beta-Adrenoceptor Agonists

SALBUTAMOL				
Aerosol inhaler, 100 mcg per dose CFC free – Up to 1000 dose available on a PSO	3.80	200 dose OP	✓	Respigen
	(6.20)		✓	SalAir Ventolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO	8.96	20	✓	Asthalin
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO	9.43	20	✓	Asthalin
TERBUTALINE SULPHATE				
Powder for inhalation, 200 mcg per dose (equivalent to 250 mcg metered dose), breath activated	22.20	120 dose OP	✓	Bricanyl Turbuhaler

Anticholinergic Agents

IPRATROPIUM BROMIDE				
Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dose available on a PSO	16.20	200 dose OP	✓	Atrovent
Nebuliser soln, 250 mcg per ml, 2 ml ampoule – Up to 40 neb available on a PSO	11.73	20	✓	Univent
	28.20		✓	Accord <small>S29</small>

Inhaled Beta-Adrenoceptor Agonists with Anticholinergic Agents

SALBUTAMOL WITH IPRATROPIUM BROMIDE				
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg per dose CFC-free	12.19	200 dose OP	✓	Duolin HFA
Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per vial, 2.5 ml ampoule – Up to 20 neb available on a PSO	11.04	20	✓	Duolin

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Long-Acting Muscarinic Antagonists

GLYCOPYRRONIUM – Subsidy by endorsement

- Inhaled glycopyrronium treatment will not be subsidised if patient is also receiving treatment with subsidised tiotropium or umeclidinium.
 - Glycopyrronium powder for inhalation 50 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly.
- Powder for inhalation 50 mcg per dose 61.00 30 dose OP ✓ **Seebri Breezhaler**

TIOTROPIUM BROMIDE – Subsidy by endorsement

- Tiotropium treatment will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or umeclidinium.
 - Tiotropium bromide is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly. Patients who had tiotropium dispensed before 1 October 2018 with a valid Special Authority are deemed endorsed.
- Powder for inhalation, 18 mcg per dose 50.37 30 dose ✓ **Spiriva**
Soln for inhalation 2.5 mcg per dose 50.37 60 dose OP ✓ **Spiriva Respimat**

UMECLIDINIUM – Subsidy by endorsement

- Umeclidinium will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or tiotropium bromide.
 - Umeclidinium powder for inhalation 62.5 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly.
- Powder for inhalation 62.5 mcg per dose 61.50 30 dose OP ✓ **Incruse Ellipta**

Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists

Combination long acting muscarinic antagonist and long acting beta-2 agonist will not be subsidised if patient is also receiving treatment with a combination inhaled corticosteroid and long acting beta-2 agonist.

►SA1584 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Both:

- Patient has been stabilised on a long acting muscarinic antagonist; and
- The prescriber considers that the patient would receive additional benefit from switching to a combination product.

Renewal from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- Patient is compliant with the medication; and
- Patient has experienced improved COPD symptom control (prescriber determined).

GLYCOPYRRONIUM WITH INDACATEROL – Special Authority see [SA1584 above](#) – Retail pharmacy

Powder for Inhalation 50 mcg with indacaterol 110 mcg 81.00 30 dose OP ✓ **Ultibro Breezhaler**

TIOTROPIUM BROMIDE WITH OLODATEROL – Special Authority see [SA1584 above](#) – Retail pharmacy

Soln for inhalation 2.5 mcg with olodaterol 2.5 mcg 81.00 60 dose OP ✓ **Spiolto Respimat**

UMECLIDINIUM WITH VILANTEROL – Special Authority see [SA1584 above](#) – Retail pharmacy

Powder for inhalation 62.5 mcg with vilanterol 25 mcg 77.00 30 dose OP ✓ **Anoro Ellipta**

Antifibrotics

NINTEDANIB – Special Authority see [SA2012 on the next page](#) – Retail pharmacy

Note: Nintedanib not subsidised in combination with subsidised pirfenidone.

Cap 100 mg 2,554.00 60 OP ✓ **Ofev**
Cap 150 mg 3,870.00 60 OP ✓ **Ofev**

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA2012 Special Authority for Subsidy

Initial application — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

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).

Renewal — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

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.

PIRFENIDONE – Retail pharmacy-Specialist – Special Authority see [SA2013 below](#)

Note: Pirfenidone is not subsidised in combination with subsidised nintedanib.

Tab 801 mg	3,645.00	90	✓ Esbriet
Tab 267 mg	1,215.00	90	✓ Esbriet

►SA2013 Special Authority for Subsidy

Initial application — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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

Renewal — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Leukotriene Receptor Antagonists

MONTELUKAST

* Tab 4 mg	3.10	28	✓	Montelukast Mylan
Montelukast Mylan to be Principal Supply on 1 December 2022				
* Tab 5 mg	3.10	28	✓	Montelukast Mylan
Montelukast Mylan to be Principal Supply on 1 December 2022				
* Tab 10 mg	2.90	28	✓	Montelukast Mylan
Montelukast Mylan to be Principal Supply on 1 December 2022				

Methylxanthines

AMINOPHYLLINE

* Inj 25 mg per ml, 10 ml ampoule – Up to 5 inj available on a PSO	180.00	5	✓	DBL Aminophylline
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THEOPHYLLINE

* Tab long-acting 250 mg	23.02	100	✓	Nuelin-SR
* Oral liq 80 mg per 15 ml	16.60	500 ml	✓	Nuelin

Mucolytics

DORNASE ALFA – Special Authority see [SA1978 below](#) – Retail pharmacy

Nebuliser soln, 2.5 mg per 2.5 ml ampoule	250.00	6	✓	Pulmozyme
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► [SA1978](#) Special Authority for Subsidy

Initial application — (cystic fibrosis) only from a respiratory physician or paediatrician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a confirmed diagnosis of cystic fibrosis; and
- 2 Patient has previously undergone a trial with, or is currently being treated with, hypertonic saline; and
- 3 Any of the following:
 - 3.1 Patient has required one or more hospital inpatient respiratory admissions in the previous 12 month period; or
 - 3.2 Patient has had 3 exacerbations due to CF, requiring oral or intravenous (IV) antibiotics in the previous 12 month period; or
 - 3.3 Patient has had 1 exacerbation due to CF, requiring oral or IV antibiotics in the previous 12 month period and a
Brasfield score of < 22/25; or
 - 3.4 Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA).

Renewal — (cystic fibrosis) only from a respiratory physician or paediatrician. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient continues to benefit from treatment.

IVACAFTOR – PCT only – Specialist – Special Authority see [SA2017 below](#)

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

► [SA2017](#) Special Authority for Subsidy

Initial application only from a respiratory specialist or paediatrician. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with cystic fibrosis; and
- 2 Either:

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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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continued...

- 2.1 Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; or
- 2.2 Patient must have other gating (class III) mutation (G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N and S549R) in the CFTR gene on at least 1 allele; and
- 3 Patients must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
- 4 Treatment with ivacaftor must be given concomitantly with standard therapy for this condition; and
- 5 Patient must not have an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing treatment with ivacaftor; and
- 6 The dose of ivacaftor will not exceed one tablet or one sachet twice daily; and
- 7 Applicant has experience and expertise in the management of cystic fibrosis.

SODIUM CHLORIDE

Not funded for use as a nasal drop.

Soln 7%24.50 90 ml OP ✓ Biomed

Nasal Preparations

Allergy Prophylactics

BUDESONIDE

Metered aqueous nasal spray, 50 mcg per dose2.54 200 dose OP ✓ SteroClear

Metered aqueous nasal spray, 100 mcg per dose2.84 200 dose OP ✓ SteroClear

FLUTICASONE PROPIONATE

Metered aqueous nasal spray, 50 mcg per dose1.98 120 dose OP ✓ Flixonase Hayfever & Allergy

IPRATROPIUM BROMIDE

Aqueous nasal spray, 0.03%.....5.23 15 ml OP ✓ Univent

Respiratory Devices

MASK FOR SPACER DEVICE

a) Up to 50 dev available on a PSO

b) Only on a PSO

c) Only for children aged six years and under

Small.....2.20 1 ✓ e-chamber Mask

PEAK FLOW METER

a) Up to 25 dev available on a PSO

b) Only on a PSO

Low range.....9.54 1 ✓ Mini-Wright AFS
Low Range

Normal range.....9.54 1 ✓ Mini-Wright
Standard

SPACER DEVICE

a) Up to 50 dev available on a PSO

b) Only on a PSO

220 ml (single patient)2.95 1 ✓ e-chamber Turbo

510 ml (single patient)5.12 1 ✓ e-chamber La
Grande

800 ml.....6.50 1 ✓ Volumatic

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Respiratory Stimulants

CAFFEINE CITRATE			
Oral liq 20 mg per ml (10 mg base per ml)	15.10	25 ml OP	✓ Biomed

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Ear Preparations

FLUMETASONE PIVALATE

Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP	✓ Locacorten-Viaform ED's
			✓ Locorten-Vioform

TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN

Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g	5.16	7.5 ml OP	✓ Kenacomb
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Ear/Eye Preparations

DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN

Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml	4.50 (9.27)	8 ml OP	Sofradex
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FRAMYCETIN SULPHATE

Ear/Eye drops 0.5%.....	4.13 (8.65)	8 ml OP	Soframycin
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Eye Preparations

Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.

Anti-Infective Preparations

ACICLOVIR

* Eye oint 3%	14.88	4.5 g OP	✓ ViruPOS
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CHLORAMPHENICOL

Eye oint 1%	1.09	5 g OP	✓ Devatis
Devatis to be Principal Supply on 1 December 2022			
Eye drops 0.5%.....	1.54	10 ml OP	✓ Chlorafast
Funded for use in the ear*. Indications marked with * are unapproved indications.			

CIPROFLOXACIN

Eye drops 0.3% – Subsidy by endorsement.....	9.73	5 ml OP	✓ Ciprofloxacin Teva
When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly.			
Note: Indication marked with a * is an unapproved indication.			

GENTAMICIN SULPHATE

Eye drops 0.3%	11.40	5 ml OP	✓ Genoptic
(Genoptic Eye drops 0.3% to be delisted 1 August 2023)			

PROPAMIDINE ISETHIONATE

* Eye drops 0.1%	2.97 (14.55)	10 ml OP	Brolene
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SODIUM FUSIDATE [FUSIDIC ACID]

Eye drops 1%	5.29	5 g OP	✓ Fucithalmic
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TOBRAMYCIN

Eye oint 0.3%	10.45	3.5 g OP	✓ Tobrex
Eye drops 0.3%	11.48	5 ml OP	✓ Tobrex

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Corticosteroids and Other Anti-Inflammatory Preparations				
DEXAMETHASONE				
* Eye oint 0.1%	5.86	3.5 g OP	✓	Maxidex
* Eye drops 0.1%	4.50	5 ml OP	✓	Maxidex
Ocular implant 700 mcg – Special Authority see SA1680 below				
– Retail pharmacy.....	1,444.50	1	✓	Ozurdex
➔SA1680 Special Authority for Subsidy				
Initial application — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:				
All of the following:				
1 Patient has diabetic macular oedema with pseudophakic lens; and				
2 Patient has reduced visual acuity of between 6/9 - 6/48 with functional awareness of reduction in vision; and				
3 Either:				
3.1 Patient's disease has progressed despite 3 injections with bevacizumab; or				
3.2 Patient is unsuitable or contraindicated to treatment with anti-VEGF agents; and				
4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.				
Renewal — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:				
Both:				
1 Patient's vision is stable or has improved (prescriber determined); and				
2 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.				
Initial application — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:				
All of the following:				
1 Patient has diabetic macular oedema; and				
2 Patient has reduced visual acuity of between 6/9 - 6/48 with functional awareness of reduction in vision; and				
3 Patient is of child bearing potential and has not yet completed a family; and				
4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.				
Renewal — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:				
All of the following:				
1 Patient's vision is stable or has improved (prescriber determined); and				
2 Patient is of child bearing potential and has not yet completed a family; and				
3 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.				
DEXAMETHASONE WITH NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE				
* Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per g.....	5.39	3.5 g OP	✓	Maxitrol
* Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per ml.....	4.50	5 ml OP	✓	Maxitrol
DICLOFENAC SODIUM				
Eye drops 0.1%	8.80	5 ml OP	✓	Voltaren Ophtha
FLUOROMETHOLONE				
* Eye drops 0.1%	3.09	5 ml OP	✓	FML
	5.20		✓	Flucon

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LEVOCABASTINE				
Eye drops 0.5 mg per ml	8.71 (10.34)	4 ml OP		Livostin
LODOXAMIDE				
Eye drops 0.1%	8.71	10 ml OP	✓	Lomide
PREDNISOLONE ACETATE				
Eye drops 1%	6.92 7.00	10 ml OP 5 ml OP	✓	Prednisolone-AFT Pred Forte
PREDNISOLONE SODIUM PHOSPHATE – Special Authority see SA1715 below – Retail pharmacy				
Eye drops 0.5%, single dose (preservative free)	38.50	20 dose	✓	Minims Prednisolone

► **SA1715** **Special Authority for Subsidy**

Initial application only from an ophthalmologist or optometrist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has severe inflammation; and
- 2 Patient has a confirmed allergic reaction to preservative in eye drops.

Renewal from any relevant practitioner. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefiting from treatment.

SODIUM CROMOGLICATE

Eye drops 2%	1.79	5 ml OP	✓	Rexacrom
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Glaucoma Preparations - Beta Blockers

BETAXOLOL

* Eye drops 0.25%	11.80	5 ml OP	✓	Betoptic S
* Eye drops 0.5%	7.50	5 ml OP	✓	Betoptic

TIMOLOL

* Eye drops 0.25%	1.81	5 ml OP	✓	Arrow-Timolol
* Eye drops 0.5%	2.04	5 ml OP	✓	Arrow-Timolol
* Eye drops 0.5%, gel forming	3.78	2.5 ml OP	✓	Timoptol XE

Glaucoma Preparations - Carbonic Anhydrase Inhibitors

ACETAZOLAMIDE

* Tab 250 mg	17.03	100	✓	Diamox
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BRINZOLAMIDE

* Eye drops 1%	7.30	5 ml OP	✓	Azopt
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DORZOLAMIDE HYDROCHLORIDE

* Eye drops 2%	9.77 (17.44)	5 ml OP		Trusopt
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DORZOLAMIDE WITH TIMOLOL

* Eye drops 2% with timolol 0.5%	2.73	5 ml OP	✓	Dortimopt
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Glaucoma Preparations - Prostaglandin Analogues

BIMATOPROST

* Eye drops 0.03%	5.95	3 ml OP	✓	Bimatoprost Multichem
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▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

* Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LATANOPROST				
* Eye drops 0.005%	1.82	2.5 ml OP	✓	Teva
TRAVOPROST				
* Eye drops 0.004%	9.75	2.5 ml OP	✓	Travatan

Glaucoma Preparations - Other

BRIMONIDINE TARTRATE				
* Eye drops 0.2%	4.29	5 ml OP	✓	Arrow-Brimonidine
BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE				
* Eye drops 0.2% with timolol maleate 0.5%	18.50	5 ml OP	✓	Combigan
LATANOPROST WITH TIMOLOL				
Eye drops 0.005% with timolol 0.5%	2.49	2.5 ml OP	✓	Arrow - Lattim
PILOCARPINE HYDROCHLORIDE				
* Eye drops 1%	4.26	15 ml OP	✓	Isopto Carpine
* Eye drops 2%	5.35	15 ml OP	✓	Isopto Carpine
* Eye drops 4%	7.99	15 ml OP	✓	Isopto Carpine
Subsidised for oral use pursuant to the Standard Formulae.				
* Eye drops 2% single dose – Special Authority see SA0895 below – Retail pharmacy	31.95	20 dose	✓	Minims Pilocarpine

► [SA0895](#) Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Either:

- 1 Patient has to use an unpreserved solution due to an allergy to the preservative; or
- 2 Patient wears soft contact lenses.

Note: Minims for a general practice are considered to be “tools of trade” and are not approved as special authority items.

Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Mydriatics and Cycloplegics

ATROPINE SULPHATE				
* Eye drops 1%	17.36	15 ml OP	✓	Atropt
CYCLOPENTOLATE HYDROCHLORIDE				
* Eye drops 1%	8.76	15 ml OP	✓	Cyclogyl
TROPICAMIDE				
* Eye drops 0.5%	7.15	15 ml OP	✓	Mydriacyl
* Eye drops 1%	8.66	15 ml OP	✓	Mydriacyl

Preparations for Tear Deficiency

For acetylcysteine eye drops refer Standard Formulae, [page 246](#)

HYPROMELLOSE				
* Eye drops 0.5%	19.50	15 ml OP	✓	Methopt
HYPROMELLOSE WITH DEXTRAN				
* Eye drops 0.3% with dextran 0.1%	2.30	15 ml OP	✓	Poly-Tears

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Preservative Free Ocular Lubricants

►SA2134 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Confirmed diagnosis by slit lamp or Schirmer test of severe secretory dry eye; and
- 2 Either:
 - 2.1 Patient is using eye drops more than four times daily on a regular basis; or
 - 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

Renewal from any relevant practitioner. Approvals valid for 24 months where the patient continues to require lubricating eye drops and has benefited from treatment.

CARBOMER – Special Authority see SA2134 above – Retail pharmacy

Ophthalmic gel 0.3%, 0.5 g	8.25	30	✓ Poly-Gel
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MACROGOL 400 AND PROPYLENE GLYCOL – Special Authority see SA2134 above – Retail pharmacy

Eye drops 0.4% and propylene glycol 0.3%, 0.4 ml	4.30	24	✓ Systane Unit Dose
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SODIUM HYALURONATE [HYALURONIC ACID] – Special Authority see SA2134 above – Retail pharmacy

Eye drops 1 mg per ml	13.85	10 ml OP	✓ Hylo-Fresh
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Hylo-Fresh has a 6 month expiry after opening. The Pharmacy Procedures Manual restriction allowing one bottle per month is not relevant and therefore only the prescribed dosage to the nearest OP may be claimed.

Other Eye Preparations

NAPHAZOLINE HYDROCHLORIDE

* Eye drops 0.1%	4.15	15 ml OP	✓ Naphcon Forte
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OLOPATADINE

Eye drops 0.1%	2.17	5 ml OP	✓ Olopatadine Teva
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Olopatadine Teva to be Principal Supply on 1 December 2022

PARAFFIN LIQUID WITH WOOL FAT

* Eye oint 3% with wool fat 3%	3.63	3.5 g OP	✓ Poly-Visc
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RETINOL PALMITATE

Eye oint 138 mcg per g	3.80	5 g OP	✓ Vita-POS
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Various

PHARMACY SERVICES

May only be claimed once per patient.

* Brand switch fee 4.50 1 fee ✓ **BSF Aspen**

The Pharmacode for BSF Aspen is 2641356 - see also [page 137](#)

(BSF Aspen Brand switch fee to be delisted 1 November 2022)

Agents Used in the Treatment of Poisonings

Antidotes

ACETYL CYSTEINE

Inj 200 mg per ml, 10 ml ampoule	52.88	10	✓ Martindale Pharma
	58.76		✓ DBL Acetylcysteine
			✓ Martindale Pharma
			S29

Martindale Pharma to be Principal Supply on 1 December 2022

(DBL Acetylcysteine Inj 200 mg per ml, 10 ml ampoule to be delisted 1 December 2022)

(Martindale Pharma S29 Inj 200 mg per ml, 10 ml ampoule to be delisted 1 December 2022)

NALOXONE HYDROCHLORIDE

a) Up to 5 inj available on a PSO

b) Only on a PSO

* Inj 400 mcg per ml, 1 ml ampoule	22.60	5	✓ DBL Naloxone Hydrochloride
	35.26	10	✓ Hameln

(DBL Naloxone Hydrochloride Inj 400 mcg per ml, 1 ml ampoule to be delisted 1 February 2023)

Removal and Elimination

CHARCOAL

* Oral liq 50 g per 250 ml	43.50	250 ml OP	✓ Carbosorb-X
a) Up to 250 ml available on a PSO			
b) Only on a PSO			

DEFERASIROX – Special Authority see [SA1492 below](#) – Retail pharmacy

Wastage claimable

Tab 125 mg dispersible	276.00	28	✓ Exjade
Tab 250 mg dispersible	552.00	28	✓ Exjade
Tab 500 mg dispersible	1,105.00	28	✓ Exjade

► [SA1492](#) Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; and
- 2 Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day; and
- 3 Any of the following:
 - 3.1 Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2*; or
 - 3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 3.3 Treatment with deferiprone has resulted in arthritis; or
- 3.4 Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per μL) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 - 1.0 cells per μL).

Renewal only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels; or
- 2 For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels.

DEFERIPRONE – Special Authority see [SA1480 below](#) – Retail pharmacy

Tab 500 mg	533.17	100	✓ Ferriprox
Oral liq 100 mg per 1 ml	266.59	250 ml OP	✓ Ferriprox

► **SA1480 Special Authority for Subsidy**

Initial application only from a haematologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; or
- 2 The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia.

DEFERIOXAMINE MESILATE

* Inj 500 mg vial	151.31	10	✓ DBL Desferrioxamine Mesylate for Inj BP ✓ Deferoxamine Pfizer S29 <small>S29</small>
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SODIUM CALCIUM EDETATE

* Inj 200 mg per ml, 5 ml	53.31 (156.71)	6	Calcium Disodium Versenate
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Standard Formulae

ACETYLCYSTEINE EYE DROPS

Acetylcysteine inj 200 mg per ml, 10 ml	qs
Suitable eye drop base	qs

CODEINE LINCTUS (3 mg per 5 ml)

Codeine phosphate	60 mg
Glycerol	40 ml
Preservative	qs
Water	to 100 ml

CODEINE LINCTUS (15 mg per 5 ml)

Codeine phosphate	300 mg
Glycerol	40 ml
Preservative	qs
Water	to 100 ml

FOLINIC MOUTHWASH

Calcium folinate 15 mg tab	1 tab
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days. Maximum 500 ml per prescription.)

METHADONE MIXTURE

Methadone powder	qs
Glycerol	qs
Water	to 100 ml

METHYL HYDROXYBENZOATE 10% SOLUTION

Methyl hydroxybenzoate	10 g
Propylene glycol	to 100 ml

(Use 1 ml of the 10% solution per 100 ml of oral liquid mixture)

OMEPRAZOLE SUSPENSION

Omeprazole capsules or powder	qs
Sodium bicarbonate powder BP	8.4 g
Water	to 100 ml

PHENOBARBITONE ORAL LIQUID

Phenobarbitone Sodium	1 g
Glycerol BP	70 ml
Water	to 100 ml

PHENOBARBITONE SODIUM PAEDIATRIC ORAL LIQUID (10 mg per ml)

Phenobarbitone Sodium	400 mg
Glycerol BP	4 ml
Water	to 40 ml

PILOCARPINE ORAL LIQUID

Pilocarpine 4% eye drops	qs
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days.)

SALIVA SUBSTITUTE FORMULA

Methylcellulose	5 g
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days. Maximum 500 ml per prescription.)

SODIUM CHLORIDE ORAL LIQUID

Sodium chloride inj 23.4%, 20 ml	qs
Water	qs

(Only funded if prescribed for treatment of hyponatraemia)

VANCOMYCIN ORAL SOLUTION (50 mg per ml)

Vancomycin 500 mg injection	10 vials
Glycerol BP	40 ml
Water	to 100 ml

(Only funded if prescribed for treatment of Clostridium difficile following metronidazole failure)

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
Extemporaneously Compounded Preparations and Galenicals			
CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency			
Powder – Only in combination.....	63.09 (90.09)	25 g	Douglas
Only in extemporaneously compounded codeine linctus.			
COLLODION FLEXIBLE			
Note: This product is no longer being manufactured by the supplier and will be delisted from the Schedule at a date to be determined.			
Collodion flexible	19.30	100 ml	✓ PSM
COMPOUND HYDROXYBENZOATE – Only in combination			
Only in extemporaneously compounded oral mixtures.			
Soln	30.00	100 ml	✓ Midwest
GLYCERIN WITH SODIUM SACCHARIN – Only in combination			
Only in combination with Ora-Plus.			
Suspension.....	30.95	473 ml	✓ Ora-Sweet SF
GLYCERIN WITH SUCROSE – Only in combination			
Only in combination with Ora-Plus.			
Suspension.....	30.95	473 ml	✓ Ora-Sweet
GLYCEROL			
* Liquid – Only in combination	3.23	500 ml	✓ <u>healthE Glycerol BP</u>
Only in extemporaneously compounded oral liquid preparations.			
METHADONE HYDROCHLORIDE			
a) Only on a controlled drug form			
b) No patient co-payment payable			
c) Safety medicine; prescriber may determine dispensing frequency			
d) Extemporaneously compounded methadone will only be reimbursed at the rate of the cheapest form available (methadone powder, not methadone tablets).			
Powder	7.84	1 g	✓ AFT
METHYL HYDROXYBENZOATE			
Powder	8.98	25 g	✓ Midwest
METHYLCELLULOSE			
Powder	36.95	100 g	✓ MidWest
Suspension – Only in combination	30.95	473 ml	✓ Ora-Plus
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHARIN – Only in combination			
Suspension.....	30.95	473 ml	✓ Ora-Blend SF
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE – Only in combination			
Suspension.....	30.95	473 ml	✓ Ora-Blend
PHENOBARBITONE SODIUM			
Powder – Only in combination.....	52.50	10 g	✓ MidWest
	325.00	100 g	✓ MidWest
Only in children up to 12 years			
PROPYLENE GLYCOL			
Only in extemporaneously compounded methyl hydroxybenzoate 10% solution.			
Liq.....	11.25	500 ml	✓ Midwest
SODIUM BICARBONATE			
Powder BP – Only in combination.....	10.05	500 g	✓ Midwest
Only in extemporaneously compounded omeprazole and lansoprazole suspension.			

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

*Three months or six months, as applicable, dispensed all-at-once



EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
SYRUP (PHARMACEUTICAL GRADE) – Only in combination				
Only in extemporaneously compounded oral liquid preparations.				
Liq.....	14.95	500 ml	✓	Midwest
WATER				
Tap – Only in combination.....	0.00	1 ml	✓	Tap water

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Nutrient Modules

Carbohydrate

►SA1930 Special Authority for Subsidy

Initial application — (Cystic fibrosis or kidney disease) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Either:

- 1 cystic fibrosis; or
- 2 chronic kidney disease.

Initial application — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 cancer in children; or
- 2 cancers affecting alimentary tract where there are malabsorption problems in patients over the age of 20 years; or
- 3 faltering growth in an infant/child; or
- 4 bronchopulmonary dysplasia; or
- 5 premature and post premature infant; or
- 6 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism.

Renewal — (Cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE SUPPLEMENT – Special Authority see SA1930 above – Hospital pharmacy [HP3]

Powder 5.29 400 g OP ✓ Polycal

Carbohydrate And Fat

►SA1376 Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

continued...

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 1 Infant or child aged four years or under; and
- 2 cystic fibrosis.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 infant or child aged four years or under; and
- 2 Any of the following:
 - 2.1 cancer in children; or
 - 2.2 faltering growth; or
 - 2.3 bronchopulmonary dysplasia; or
 - 2.4 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE AND FAT SUPPLEMENT – Special Authority see [SA1376 on the previous page](#) – Hospital pharmacy [HP3]

Powder (neutral)	60.31	400 g OP	✓ Duocal Super Soluble Powder
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Fat

»SA1523 Special Authority for Subsidy

Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has inborn errors of metabolism.

Initial application — (Indications other than inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 faltering growth in an infant/child; or
- 2 bronchopulmonary dysplasia; or
- 3 fat malabsorption; or
- 4 lymphangiectasia; or
- 5 short bowel syndrome; or
- 6 infants with necrotising enterocolitis; or
- 7 biliary atresia; or
- 8 for use in a ketogenic diet; or
- 9 chyle leak; or

continued...

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

10 ascites; or

11 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Renewal — (Inborn errors of metabolism) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner.

Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than inborn errors of metabolism) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT SUPPLEMENT – Special Authority see [SA1523 on the previous page](#) – Hospital pharmacy [HP3]

Emulsion (neutral)	12.30	200 ml OP	✓ Calogen
	30.75	500 ml OP	✓ Calogen
Emulsion (strawberry).....	12.30	200 ml OP	✓ Calogen
Oil	30.00	500 ml OP	✓ MCT oil (Nutricia)
Oil, 250 ml	114.92	4 OP	✓ Liquigen

Protein

►SA1524 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 protein losing enteropathy; or
- 2 high protein needs; or
- 3 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PROTEIN SUPPLEMENT – Special Authority see [SA1524 above](#) – Hospital pharmacy [HP3]

Powder	7.90	225 g OP	✓ Protifar
	8.95	227 g OP	✓ Resouce Beneprotein

Oral and Enteral Feeds

Diabetic Products

►SA1095 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is a type I or and II diabetic who is suffering weight loss and malnutrition that requires nutritional support.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

- Both:
- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
 - 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

DIABETIC ENTERAL FEED 1KCAL/ML – Special Authority see [SA1095 above](#) – Hospital pharmacy [HP3]

Liquid.....	3.75	500 ml OP	✓ Glucerna Select
	7.50	1,000 ml OP	✓ Diason RTH
			✓ Nutrison Advanced Diason

(Diason RTH Liquid to be delisted 1 December 2022)

DIABETIC ORAL FEED 1KCAL/ML – Special Authority see [SA1095 above](#) – Hospital pharmacy [HP3]

Liquid (strawberry).....	1.50	200 ml OP	✓ Diasip
Liquid (vanilla).....	1.50	200 ml OP	✓ Diasip
	2.10		✓ Nutren Diabetes

Fat Modified Products

►SA1525 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Patient has metabolic disorders of fat metabolism; or
- 2 Patient has a chyle leak; or
- 3 Modified as a modular feed, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule, for adults.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

- Both:
- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
 - 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT MODIFIED FEED – Special Authority see [SA1525 above](#) – Hospital pharmacy [HP3]

Powder	60.48	400 g OP	✓ Monogen
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Paediatric Products For Children Awaiting Liver Transplant

►SA1098 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) who requires a liver transplant.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see [SA1098 above](#) – Hospital pharmacy [HP3]

Powder (unflavoured) 78.97 400 g OP ✓ **Heparon Junior**

Paediatric Products For Children With Chronic Renal Failure

►SA1099 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) with acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see [SA1099 above](#) – Hospital pharmacy [HP3]

Powder 54.00 400 g OP ✓ **Kindergen**

Paediatric Products

►SA1379 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child is aged one to ten years; and
- 2 Any of the following:
 - 2.1 the child is being fed via a tube or a tube is to be inserted for the purposes of feeding; or
 - 2.2 any condition causing malabsorption; or
 - 2.3 faltering growth in an infant/child; or
 - 2.4 increased nutritional requirements; or
 - 2.5 the child is being transitioned from TPN or tube feeding to oral feeding.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
continued...				
applications meeting the following criteria:				
Both:				
1 The treatment remains appropriate and the patient is benefiting from treatment; and				
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.				
PAEDIATRIC ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1379 on the previous page – Hospital pharmacy [HP3]				
Liquid.....	6.00	500 ml OP	✓	Nutrini Energy RTH
PAEDIATRIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1379 on the previous page – Hospital pharmacy [HP3]				
Liquid.....	2.68	500 ml OP	✓	Nutrini RTH
			✓	Pediasure RTH
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1379 on the previous page – Hospital pharmacy [HP3]				
Liquid.....	6.00	500 ml OP	✓	Nutrini Energy Multi Fibre
PAEDIATRIC ORAL FEED 1.5KCAL/ML – Special Authority see SA1379 on the previous page – Hospital pharmacy [HP3]				
Liquid (strawberry).....	1.60	200 ml OP	✓	Fortini
Liquid (vanilla)	1.60	200 ml OP	✓	Fortini
PAEDIATRIC ORAL FEED 1KCAL/ML – Special Authority see SA1379 on the previous page – Hospital pharmacy [HP3]				
Liquid (chocolate)	1.07	200 ml OP	✓	Pediasure
Liquid (strawberry).....	1.07	200 ml OP	✓	Pediasure
Liquid (vanilla)	1.07	200 ml OP	✓	Pediasure
	1.34	250 ml OP	✓	Pediasure
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1379 on the previous page – Hospital pharmacy [HP3]				
Liquid (unflavoured).....	1.60	200 ml OP	✓	Fortini Multi Fibre
Liquid (chocolate)	1.60	200 ml OP	✓	Fortini Multi Fibre
Liquid (strawberry).....	1.60	200 ml OP	✓	Fortini Multi Fibre
Liquid (vanilla)	1.60	200 ml OP	✓	Fortini Multi Fibre
PEPTIDE-BASED ORAL FEED – Special Authority see SA1379 on the previous page – Hospital pharmacy [HP3]				
Powder	43.60	400 g OP	✓	Peptamen Junior

Renal Products

►SA1101 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

- Both:
- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
 - 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

RENAL ENTERAL FEED 1.8 KCAL/ML – Special Authority see [SA1101 above](#) – Hospital pharmacy [HP3]

Liquid..... 6.08 500 ml OP ✓ Nepro HP RTH

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
RENAL ORAL FEED 1.8 KCAL/ML – Special Authority see SA1101 on the previous page – Hospital pharmacy [HP3]			
Liquid	2.67	220 ml OP	✓ Nepro HP (strawberry) ✓ Nepro HP (vanilla)
RENAL ORAL FEED 2 KCAL/ML – Special Authority see SA1101 on the previous page – Hospital pharmacy [HP3]			
Liquid, 200 ml bottle	11.52 (13.24)	4 OP	NovaSource Renal
Liquid (apricot) 125 ml	11.52	4 OP	✓ Renilon 7.5
Liquid (caramel) 125 ml	11.52	4 OP	✓ Renilon 7.5

Specialised And Elemental Products

► [SA1377](#) Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 malabsorption; or
- 2 short bowel syndrome; or
- 3 enterocutaneous fistulas; or
- 4 eosinophilic oesophagitis; or
- 5 inflammatory bowel disease; or
- 6 patients with multiple food allergies requiring enteral feeding.

Notes: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation.

Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML – Special Authority see [SA1377 above](#) – Hospital pharmacy [HP3]

Liquid 18.06 1,000 ml OP ✓ **Vital**

ORAL ELEMENTAL FEED 0.8KCAL/ML – Special Authority see [SA1377 above](#) – Hospital pharmacy [HP3]

Liquid (grapefruit), 250 ml carton..... 171.00 18 OP ✓ **Elemental 028 Extra**

Liquid (pineapple & orange), 250 ml carton..... 171.00 18 OP ✓ **Elemental 028 Extra**

Liquid (summer fruits), 250 ml carton..... 171.00 18 OP ✓ **Elemental 028 Extra**

ORAL ELEMENTAL FEED 1KCAL/ML – Special Authority see [SA1377 above](#) – Hospital pharmacy [HP3]

Powder (unflavoured) 4.50 80 g OP ✓ **Vivonex TEN**

SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML – Special Authority see [SA1377 above](#) – Hospital pharmacy [HP3]

Liquid 12.04 1,000 ml OP ✓ **Nutrison Advanced**
Peptisorb

✓ **Peptisorb**

(Peptisorb Liquid to be delisted 1 June 2023)

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Paediatric Products For Children With Low Energy Requirements

►SA1196 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child aged one to eight years; and
- 2 The child has a low energy requirement but normal protein and micronutrient requirements.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED WITH FIBRE 0.76 KCAL/ML – Special Authority see SA1196 above – Hospital pharmacy [HP3]
Liquid.....4.00 500 ml OP ✓ **Nutrini Low Energy**
Multi Fibre

Standard Supplements

►SA1859 Special Authority for Subsidy

Initial application — (Children - indications other than exclusive enteral nutrition for Crohn's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 Any of the following:
 - 2.1 The patient has a condition causing malabsorption; or
 - 2.2 The patient has failure to thrive; or
 - 2.3 The patient has increased nutritional requirements; and
- 3 Nutrition goal has been set (eg reach a specific weight or BMI).

Renewal — (Children - indications other than exclusive enteral nutrition for Crohn's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 A nutrition goal has been set (eg reach a specific weight or BMI).

Initial application — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist or dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 Dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

Renewal — (Children - exclusive enteral nutrition for Crohn's disease) from any relevant practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

Initial application — (Adults) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - Patient is Malnourished
 - 1.1 Patient has a body mass index (BMI) of less than 18.5 kg/m²; or
 - 1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
 - 1.3 Patient has a BMI of less than 20 kg/m² and unintentional weight loss greater than 5% within the last 3-6 months; and
- 2 Any of the following:
 - Patient has not responded to first-line dietary measures over a 4 week period by:
 - 2.1 Increasing their food intake frequency (eg snacks between meals); or
 - 2.2 Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or
 - 2.3 Using over the counter supplements (e.g. Complan); and
- 3 A nutrition goal has been set (e.g. to reach a specific weight or BMI).

Renewal — (Adults) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
Both:

- 1 A nutrition goal has been set (eg reach a specific weight or BMI); and
- 2 Any of the following:
 - Patient is Malnourished
 - 2.1 Patient has a body mass index (BMI) of less than 18.5 kg/m²; or
 - 2.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
 - 2.3 Patient has a BMI of less than 20 kg/m² and unintentional weight loss greater than 5% within the last 3-6 months.

Initial application — (Short-term medical condition) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a nasogastric tube or a nasogastric tube is to be inserted for feeding; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Is undergoing a bone marrow transplant; or
- 4 Tempomandibular surgery or glossectomy; or
- 5 Both:
 - 5.1 Pregnant; and
 - 5.2 Any of the following:
 - 5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Renewal — (Short-term medical condition) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a nasogastric tube; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Has undergone a bone marrow transplant; or
- 4 Tempomandibular surgery or glossectomy; or
- 5 Both:
 - 5.1 Pregnant; and
 - 5.2 Any of the following:
 - 5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Initial application — (Long-term medical condition) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure; or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula; or
- 9 Severe chronic neurological conditions; or
- 10 Epidermolysis bullosa; or
- 11 AIDS (CD4 count < 200 cells/mm³); or
- 12 Chronic pancreatitis.

Renewal — (Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure; or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula; or
- 9 Severe chronic neurological conditions.

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]			
Liquid	1.75	250 ml OP	✓ Ensure Plus HN
	7.00	1,000 ml OP	✓ Ensure Plus RTH
			✓ Nutrison Energy
ENTERAL FEED 1KCAL/ML – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]			
Liquid	1.24	250 ml OP	✓ Isosource Standard
	5.29	1,000 ml OP	✓ Nutrison Standard RTH
			✓ Osmolite RTH
ENTERAL FEED WITH FIBRE 0.83 KCAL/ML – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]			
Liquid	5.29	1,000 ml OP	✓ Nutrison 800 Complete Multi Fibre
ENTERAL FEED WITH FIBRE 1 KCAL/ML – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]			
Liquid	5.29	1,000 ml OP	✓ Jevity RTH
			✓ Nutrison Multi Fibre
ENTERAL FEED WITH FIBRE 1.2KCAL/ML – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]			
Liquid	6.35	1,000 ml OP	✓ Jevity Plus
ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]			
Liquid	7.00	1,000 ml OP	✓ Jevity HiCal RTH
			✓ Nutrison Energy Multi Fibre
ORAL FEED (POWDER) – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]			
Powder (chocolate)	14.00	840 g OP	✓ Sustagen Hospital Formula
	26.00	850 g OP	✓ Ensure
Powder (vanilla)	14.00	840 g OP	✓ Sustagen Hospital Formula Active
	26.00	850 g OP	✓ Ensure

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ORAL FEED 1.5KCAL/ML – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]				
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, who have severe epidermolysis bullosa, or as exclusive enteral nutrition in children under the age of 18 years for the treatment of Crohn's disease, or for patients with COPD and hypercapnia, defined as CO2 value exceeding 55mmHg. The prescription must be endorsed accordingly.				
Liquid (banana) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72 (1.26) (1.26)	200 ml OP		Ensure Plus Fortisip
Liquid (chocolate) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72 (1.26) (1.26)	200 ml OP		Ensure Plus Fortisip
Liquid (fruit of the forest) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72 (1.26)	200 ml OP		Ensure Plus
Liquid (strawberry) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72 (1.26)	200 ml OP		Fortisip
Liquid (vanilla) – Higher subsidy of up to \$1.33 per 237 ml with				
Endorsement	0.85 (1.33) 0.72 (1.26) (1.26)	237 ml OP 200 ml OP		Ensure Plus Ensure Plus Fortisip
ORAL FEED WITH FIBRE 1.5 KCAL/ML – Special Authority see SA1859 on page 256 – Hospital pharmacy [HP3]				
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.				
Liquid (chocolate) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72 (1.26)	200 ml OP		Fortisip Multi Fibre
Liquid (strawberry) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72 (1.26)	200 ml OP		Fortisip Multi Fibre
Liquid (vanilla) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72 (1.26)	200 ml OP		Fortisip Multi Fibre

High Calorie Products

► [SA1195](#) Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner.

Approvals valid for 3 years for applications meeting the following criteria:

All of the following:

- 1 Cystic fibrosis; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements.

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 any condition causing malabsorption; or
 - 1.2 faltering growth in an infant/child; or
 - 1.3 increased nutritional requirements; or
 - 1.4 fluid restricted; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL FEED 2 KCAL/ML – Special Authority see [SA1195 on the previous page](#) – Hospital pharmacy [HP3]

Liquid.....	5.50	500 ml OP	✓ Nutrison Concentrated
	11.00	1,000 ml OP	✓ Ensure Two Cal HN RTH

ORAL FEED 2 KCAL/ML – Special Authority see [SA1195 on the previous page](#) – Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (vanilla) – Higher subsidy of \$1.90 per 200 ml with

Endorsement.....	0.96 (1.90)	200 ml OP	Two Cal HN
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Food Thickeners

►SA1106 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient has motor neurone disease with swallowing disorder.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
FOOD THICKENER – Special Authority see SA1106 on the previous page – Hospital pharmacy [HP3]			
Powder	6.53	300 g OP	✓ Nutilis
	7.25	380 g OP	✓ Feed Thickener Karicare Aptamil

Gluten Free Foods

The funding of gluten free foods is no longer being actively managed by Pharmac from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten free options are available through retail outlets.

» [SA1729](#) Special Authority for Subsidy

Initial application — (all patients) only from a dietitian, relevant specialist or vocationally registered general practitioner.

Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 Gluten enteropathy has been diagnosed by biopsy; or
- 2 Patient suffers from dermatitis herpetiformis.

Initial application — (paediatric patients diagnosed by ESPGHAN criteria) only from a paediatric gastroenterologist.

Approvals valid without further renewal unless notified where the paediatric patient fulfils ESPGHAN criteria for biopsy free diagnosis of coeliac disease.

GLUTEN FREE BAKING MIX – Special Authority see [SA1729 above](#) – Hospital pharmacy [HP3]

Powder	2.81	1,000 g OP	
	(5.15)		Healtheries Simple Baking Mix

GLUTEN FREE BREAD MIX – Special Authority see [SA1729 above](#) – Hospital pharmacy [HP3]

Powder	3.93	1,000 g OP	
	(7.32)		NZB Low Gluten Bread Mix
	3.51		
	(10.87)		Horleys Bread Mix

GLUTEN FREE FLOUR – Special Authority see [SA1729 above](#) – Hospital pharmacy [HP3]

Powder	5.62	2,000 g OP	
	(18.10)		Horleys Flour

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
GLUTEN FREE PASTA – Special Authority see SA1729 on the previous page – Hospital pharmacy [HP3]			
Buckwheat Spirals.....	2.00 (3.11)	250 g OP	Orgran
Corn and Vegetable Shells.....	2.00 (2.92)	250 g OP	Orgran
Corn and Vegetable Spirals.....	2.00 (2.92)	250 g OP	Orgran
Rice and Corn Lasagne Sheets.....	1.60 (3.82)	200 g OP	Orgran
Rice and Corn Macaroni.....	2.00 (2.92)	250 g OP	Orgran
Rice and Corn Penne.....	2.00 (2.92)	250 g OP	Orgran
Rice and Maize Pasta Spirals.....	2.00 (2.92)	250 g OP	Orgran
Rice and Millet Spirals.....	2.00 (3.11)	250 g OP	Orgran
Rice and corn spaghetti noodles.....	2.00 (2.92)	375 g OP	Orgran
Vegetable and Rice Spirals.....	2.00 (2.92)	250 g OP	Orgran
Italian long style spaghetti.....	2.00 (3.11)	220 g OP	Orgran

Foods And Supplements For Inborn Errors Of Metabolism

►SA1108 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Dietary management of homocystinuria; or
- 2 Dietary management of maple syrup urine disease; or
- 3 Dietary management of phenylketonuria (PKU); or
- 4 For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy.

Supplements For Homocystinuria

AMINOACID FORMULA WITHOUT METHIONINE – Special Authority see [SA1108 above](#) – Hospital pharmacy [HP3]

Powder.....461.94 500 g OP ✓ **XMET Maxamum**

Supplements For MSUD

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE – Special Authority see [SA1108 above](#) – Hospital pharmacy [HP3]

Powder.....437.22 500 g OP ✓ **MSUD Maxamum**

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Supplements For PKU				
AMINOACID FORMULA WITHOUT PHENYLALANINE – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]				
Tabs.....	99.00	75 OP	✓	Phlexy 10
Powder (orange) 36 g sachet	393.00	30	✓	PKU Anamix Junior Orange
Powder (berry) 28 g sachets	936.00	30	✓	PKU Lophlex Powder
Powder (chocolate) 36 g sachet	393.00	30	✓	PKU Anamix Junior Chocolate
Powder (neutral) 28 g sachets.....	936.00	30	✓	PKU Lophlex Powder
Powder (neutral) 36 g sachets.....	393.00	30	✓	PKU Anamix Junior
Powder (orange) 28 g sachets	936.00	30	✓	PKU Lophlex Powder
Powder (unflavoured) 28 g sachets.....	936.00	30	✓	PKU Lophlex Powder
Powder (unflavoured) 36 g sachets.....	393.00	30	✓	PKU Anamix Junior
Powder (vanilla) 36 g sachet	393.00	30	✓	PKU Anamix Junior Vanilla
Infant formula.....	174.72	400 g OP	✓	PKU Anamix Infant
Powder (orange).....	320.00	500 g OP	✓	XP Maxamum
Powder (unflavoured)	320.00	500 g OP	✓	XP Maxamum
Liquid (berry)	13.10	125 ml OP	✓	PKU Anamix Junior LQ
Liquid (orange)	13.10	125 ml OP	✓	PKU Anamix Junior LQ
Liquid (unflavoured).....	13.10	125 ml OP	✓	PKU Anamix Junior LQ
Liquid (forest berries), 250 ml carton.....	540.00	18 OP	✓	Easiphen Liquid
Liquid (juicy tropical) 125 ml	936.00	30 OP	✓	PKU Lophlex LQ 20
Oral semi-solid (berries) 109 g	1,123.20	36 OP	✓	PKU Lophlex Sensation 20
Liquid (juicy berries) 62.5 ml.....	939.00	60 OP	✓	PKU Lophlex LQ 10
Liquid (juicy citrus) 62.5 ml.....	939.00	60 OP	✓	PKU Lophlex LQ 10
Liquid (juicy orange) 62.5 ml	939.00	60 OP	✓	PKU Lophlex LQ 10
Liquid (juicy berries) 125 ml.....	936.00	30 OP	✓	PKU Lophlex LQ 20
Liquid (juicy orange) 125 ml	936.00	30 OP	✓	PKU Lophlex LQ 20
(PKU Lophlex Powder Powder (unflavoured) 28 g sachets to be delisted 1 December 2022)				
(PKU Anamix Junior Powder (unflavoured) 36 g sachets to be delisted 1 December 2022)				
Foods				
LOW PROTEIN BAKING MIX – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]				
Powder	8.22	500 g OP	✓	Loprofin Mix

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
LOW PROTEIN PASTA – Special Authority see SA1108 on page 263 – Hospital pharmacy [HP3]			
Animal shapes	11.91	500 g OP	✓ Loprofin
Lasagne	5.95	250 g OP	✓ Loprofin
Low protein rice pasta	11.91	500 g OP	✓ Loprofin
Macaroni	5.95	250 g OP	✓ Loprofin
Penne	11.91	500 g OP	✓ Loprofin
Spaghetti	11.91	500 g OP	✓ Loprofin
Spirals	11.91	500 g OP	✓ Loprofin

Infant Formulae

For Williams Syndrome

➤ [SA1110](#) Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is an infant suffering from Williams Syndrome and associated hypercalcaemia.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

LOW CALCIUM INFANT FORMULA – Special Authority see [SA1110 above](#) – Hospital pharmacy [HP3]

Powder	44.40	400 g OP	✓ Locasol
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Gastrointestinal and Other Malabsorptive Problems

AMINO ACID FORMULA – Special Authority see [SA2092 below](#) – Hospital pharmacy [HP3]

Powder	43.60	400 g OP	✓ Alfamino ✓ Alfamino Junior ✓ Elecare ✓ Elecare LCP ✓ Neocate Gold ✓ Neocate Junior Unflavoured
Powder (unflavoured)	53.00	400 g OP	✓ Neocate SYNEO ✓ Elecare ✓ Neocate Junior Vanilla
Powder (vanilla)	53.00	400 g OP	

➤ [SA2092](#) Special Authority for Subsidy

Initial application — (Infants under 12 months of age) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 History of anaphylaxis to cow's milk protein formula or dairy products; or
- 2 Eosinophilic oesophagitis; or
- 3 Ultra-short gut; or
- 4 Severe Immune deficiency; or

continued...

continued...

5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or

6 Both:

6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and

6.2 Either:

6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or

6.2.2 Patient has IgE mediated allergy.

Initial application — (Children 12 months of age and over) only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist.

Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Either:

1.1 Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist; or

1.2 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient; and

2 Any of the following:

2.1 History of anaphylaxis to cow's milk protein formula or dairy products; or

2.2 Eosinophilic oesophagitis; or

2.3 Ultra-short gut; or

2.4 Severe Immune deficiency; or

2.5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or

2.6 Both:

2.6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and

2.6.2 Either:

2.6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or

2.6.2.2 Patient has IgE mediated allergy.

Renewal — (Infants up to 12 months of age) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

1.1 Patient has IgE mediated allergy; and

1.2 All of the following:

1.2.1 Patient remains allergic to cow's milk; and

1.2.2 An assessment as to whether the infant can be transitioned to a cow's milk protein, soy or extensively hydrolysed infant formula has been undertaken; and

1.2.3 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and

1.2.4 Amino acid formula is required for a nutritional deficit; and

1.2.5 It has been more than three months from the previous approval; or

2 Both:

2.1 Patient has non IgE mediated severe gastrointestinal intolerance (including eosinophilic oesophagitis, ultra-short gut and severe immune deficiency); and

2.2 All of the following:

2.2.1 An assessment as to whether the infant can be transitioned to a cow's milk protein, soy, or extensively hydrolysed infant formula has been undertaken; and

2.2.2 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and

continued...

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

2.2.3 Amino acid formula is required for a nutritional deficit; and

2.2.4 It has been more than three months from the previous approval.

Renewal — (Children 12 months of age and over) only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist.

Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Either:

- 1.1 Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist; or
- 1.2 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient; and

2 Any of the following:

- 2.1 History of anaphylaxis to cow's milk protein formula or dairy products; or
- 2.2 Eosinophilic oesophagitis; or
- 2.3 Ultra-short gut; or
- 2.4 Severe Immune deficiency; or
- 2.5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
- 2.6 Both:

2.6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and

2.6.2 Either:

2.6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or

2.6.2.2 Patient has IgE mediated allergy.

Initial application — (for patients who have a current funding under Special Authority form SA1557) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a valid Special Authority approval for extensively hydrolysed formula (SA1557); and
- 2 Extensively hydrolysed formula (Aptamil Gold+ Pepti Junior, AllerPro SYNEO 1 and 2) is unable to be supplied at this time; and
- 3 The approval only applies to funded dispensings of Neocate Gold and Neocate Syneo.

Note: This criteria is short term funding to cover an out-of-stock situation on some extensively hydrolysed formula powder funded under Special Authority form SA1557. There is no renewal criteria under this restriction.

ENTERAL LIQUID PEPTIDE FORMULA – Special Authority see [SA1953 below](#) – Hospital pharmacy [HP3]

Liquid 1 kcal/ml.....	10.45	500 ml OP	✓ Nutrini Peptisorb
Liquid 1.5 kcal/ml.....	15.68	500 ml OP	✓ Nutrini Peptisorb Energy

➤ **SA1953** Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has impaired gastrointestinal function and either cannot tolerate polymeric feeds, or polymeric feeds are unsuitable; and
- 2 Any of the following:
 - 2.1 Severe malabsorption; or
 - 2.2 Short bowel syndrome; or

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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continued...

- 2.3 Intractable diarrhoea; or
- 2.4 Biliary atresia; or
- 2.5 Cholestatic liver diseases causing malabsorption; or
- 2.6 Cystic fibrosis; or
- 2.7 Proven fat malabsorption; or
- 2.8 Severe intestinal motility disorders causing significant malabsorption; or
- 2.9 Intestinal failure; or
- 2.10 Both:
 - 2.10.1 The patient is currently receiving funded amino acid formula; and
 - 2.10.2 The patient is to be trialled on, or transitioned to, an enteral liquid peptide formula; and

3 Either:

- 3.1 A semi-elemental or partially hydrolysed powdered feed has been reasonably trialled and considered unsuitable; or
- 3.2 For step down from intravenous nutrition.

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

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the patient can be transitioned to a cows milk protein or soy infant formula or extensively hydrolysed formula has been undertaken; and
- 2 The outcome of the assessment is that the patient continues to require an enteral liquid peptide formula; and
- 3 General practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

EXTENSIVELY HYDROLYSED FORMULA – Special Authority see [SA1557 below](#) – Hospital pharmacy [HP3]

Powder	15.21	450 g OP	✓ Aptamil Gold+ Pepti Junior
	30.42	900 g OP	✓ Pepti-Junior
			✓ Allerpro Syneo 1
			✓ Allerpro Syneo 2
			✓ Aptamil AllerPro SYNEO 1
			✓ Aptamil AllerPro SYNEO 2

(Aptamil Gold+ Pepti Junior Powder to be delisted 1 November 2022)

(Aptamil AllerPro SYNEO 1 Powder to be delisted 1 November 2022)

(Aptamil AllerPro SYNEO 2 Powder to be delisted 1 November 2022)

►SA1557 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 Both:
 - 1.1 Cows milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
 - 1.2 Either:
 - 1.2.1 Soy milk formula has been reasonably trialled without resolution of symptoms; or
 - 1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
- 2 Severe malabsorption; or

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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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continued...

- 3 Short bowel syndrome; or
- 4 Intractable diarrhoea; or
- 5 Biliary atresia; or
- 6 Cholestatic liver diseases causing malsorption; or
- 7 Cystic fibrosis; or
- 8 Proven fat malabsorption; or
- 9 Severe intestinal motility disorders causing significant malabsorption; or
- 10 Intestinal failure; or
- 11 All of the following:
 - 11.1 For step down from Amino Acid Formula; and
 - 11.2 The infant is currently receiving funded amino acid formula; and
 - 11.3 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula; and
 - 11.4 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

Note: A reasonable trial is defined as a 2-4 week trial, or signs of an immediate IgE mediated allergic reaction.
Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the infant can be transitioned to a cows milk protein or soy infant formula has been undertaken; and
- 2 The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula; and
- 3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

Fluid Restricted

PAEDIATRIC ORAL/ENTERAL FEED 1 KCAL/ML – Special Authority see [SA1698 below](#) – Hospital pharmacy [HP3]

Liquid2.35 125 ml OP ✓ **Infatrini**

»[SA1698](#) **Special Authority for Subsidy**

Initial application only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian.

Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient is fluid restricted or volume intolerant and has been diagnosed with faltering growth; and
- 2 Patient is under the care of a paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
- 3 Patient is under 18 months of age or weighs less than 8 kg.

Note: 'Volume intolerant' patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

Renewal only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient continues to be fluid restricted or volume intolerant and has faltering growth; and
- 2 Patient is under the care of a hospital paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
- 3 Patient is under 18 months of age or weighs less than 8 kg.

Note: 'Volume intolerant' patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Ketogenic Diet

»SA1197 Special Authority for Subsidy

Initial application only from a metabolic physician or paediatric neurologist. Approvals valid for 3 months where the patient has intractable epilepsy, pyruvate dehydrogenase deficiency or glucose transported type-1 deficiency and other conditions requiring a ketogenic diet.

Renewal only from a metabolic physician or paediatric neurologist. Approvals valid for 2 years where the patient is on a ketogenic diet and the patient is benefiting from the diet.

HIGH FAT LOW CARBOHYDRATE FORMULA – Special Authority see SA1197 above – Retail pharmacy

Powder (unflavoured)	35.50	300 g OP	✓ KetoCal 4:1
			✓ Ketocal 3:1
Powder (vanilla).....	35.50	300 g OP	✓ KetoCal 4:1

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Vaccinations

BACILLUS CALMETTE-GUERIN VACCINE – [Xpharm]

For infants at increased risk of tuberculosis. Increased risk is defined as:

- 1) living in a house or family with a person with current or past history of TB; or
- 2) having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or
- 3) during their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000

Note a list of countries with high rates of TB are available at www.health.govt.nz/tuberculosis (search for downloads) or www.bcgatlas.org/index.php.

Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin),

Danish strain 1331, live attenuated, vial with diluent.....	0.00	10	✓ BCG Vaccine
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DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c)

A) Funded for any of the following criteria:

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

Notes: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

B) Contractors will be entitled to claim payment from the Funder for the supply of diphtheria, tetanus and pertussis vaccine to patients eligible under the above criteria pursuant to their contract with Te Whatu Ora Health New Zealand for subsidised immunisation, and they may only do so in respect of the diphtheria, tetanus and pertussis vaccine listed in the Pharmaceutical Schedule.

C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs 1 – 9 above.

Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg

pertussis toxoid, 8 mcg pertussis filamentous

haemagglutinin and 2.5 mcg pertactin in 0.5 ml syringe	0.00	10	✓ Boostrix
		1	✓ Boostrix

NATIONAL IMMUNISATION SCHEDULE

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE – [Xpharm]				
Funded for any of the following:				
1) A single dose for children up to the age of 7 who have completed primary immunisation; or				
2) A course of four vaccines is funded for catch up programmes for children (to the age of 10 years) to complete full primary immunisation; or				
3) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or				
4) Five doses will be funded for children requiring solid organ transplantation.				
Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.				
Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5ml syringe	0.00	10	✓	<u>Infanrix IPV</u>
DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE – [Xpharm]				
Funded for patients meeting any of the following criteria:				
1) Up to four doses for children up to and under the age of 10 for primary immunisation; or				
2) An additional four doses (as appropriate) are funded for (re-)immunisation for children up to and under the age of 10 who are patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or				
3) Up to five doses for children up to and under the age of 10 receiving solid organ transplantation.				
Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.				
Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-Ag U polio virus, 10 mcg hepatitis B surface antigen in 0.5 ml syringe	0.00	10	✓	<u>Infanrix-hexa</u>
HAEMOPHILUS INFLUENZAE TYPE B VACCINE – [Xpharm]				
One dose for patients meeting any of the following:				
1) For primary vaccination in children; or				
2) An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; functional asplenic; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or				
3) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.				
Haemophilus Influenzae type B polysaccharide 10 mcg conjugated to tetanus toxoid as carrier protein 20-40 mcg; prefilled syringe plus vial 0.5 ml.....	0.00	1	✓	<u>Hiberix</u>
HEPATITIS A VACCINE – [Xpharm]				
Funded for patients meeting any of the following criteria:				
1) Two vaccinations for use in transplant patients; or				
2) Two vaccinations for use in children with chronic liver disease; or				
3) One dose of vaccine for close contacts of known hepatitis A cases.				
Inj 1440 ELISA units in 1 ml syringe.....	0.00	1	✓	<u>Havrix</u>
Inj 720 ELISA units in 0.5 ml syringe.....	0.00	1	✓	<u>Havrix Junior</u>

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
HEPATITIS B RECOMBINANT VACCINE – [Xpharm]			
Inj 10 mcg per 0.5 ml prefilled syringe.....	0.00	1	✓ Engerix-B
Funded for patients meeting any of the following criteria:			
1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or			
2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or			
3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or			
4) for HIV positive patients; or			
5) for hepatitis C positive patients; or			
6) for patients following non-consensual sexual intercourse; or			
7) for patients following immunosuppression; or			
8) for solid organ transplant patients; or			
9) for post-haematopoietic stem cell transplant (HSCT) patients; or			
10) following needle stick injury.			
Inj 20 mcg per 1 ml prefilled syringe.....	0.00	1	✓ Engerix-B
Funded for patients meeting any of the following criteria:			
1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or			
2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or			
3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or			
4) for HIV positive patients; or			
5) for hepatitis C positive patients; or			
6) for patients following non-consensual sexual intercourse; or			
7) for patients following immunosuppression; or			
8) for solid organ transplant patients; or			
9) for post-haematopoietic stem cell transplant (HSCT) patients; or			
10) following needle stick injury; or			
11) for dialysis patients; or			
12) for liver or kidney transplant patients.			
HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV] – [Xpharm]			
Any of the following:			
1) Maximum of two doses for children aged 14 years and under; or			
2) Maximum of three doses for patients meeting any of the following criteria:			
1) People aged 15 to 26 years inclusive; or			
2) Either:			
People aged 9 to 26 years inclusive			
1) Confirmed HIV infection; or			
2) Transplant (including stem cell) patients: or			
3) Maximum of four doses for people aged 9 to 26 years inclusive post chemotherapy			
Inj 270 mcg in 0.5 ml syringe.....	0.00	10	✓ Gardasil 9

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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INFLUENZA VACCINE

Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)

– [Xpharm] 11.00 1 ✓ **Afluria Quad Junior**
(2022 formulation)

A) INFLUENZA VACCINE – child aged 6 months to 35 months

is available each year for patients aged 6 months to 35 months who meet the following criteria, as set by Pharmac:

- i) have any of the following cardiovascular diseases
 - a) ischaemic heart disease, or
 - b) congestive heart failure, or
 - c) rheumatic heart disease, or
 - d) congenital heart disease, or
 - e) cerebro-vascular disease; or
- ii) have either of the following chronic respiratory diseases:
 - a) asthma, if on a regular preventative therapy, or
 - b) other chronic respiratory disease with impaired lung function; or
- iii) have diabetes; or
- iv) have chronic renal disease; or
- v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
- vi) have any of the following other conditions:
 - a) autoimmune disease, or
 - b) immune suppression or immune deficiency, or
 - c) HIV, or
 - d) transplant recipients, or
 - e) neuromuscular and CNS diseases/disorders, or
 - f) haemoglobinopathies, or
 - g) on long term aspirin, or
 - h) have a cochlear implant, or
 - i) errors of metabolism at risk of major metabolic decompensation, or
 - j) pre and post splenectomy, or
 - k) down syndrome, or
- vii) have been hospitalised for respiratory illness or have a history of significant respiratory illness;

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
 - b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Doctors are the only Contractors entitled to claim payment for the supply of influenza vaccine inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)..... 110.00

10 ✓ **Afluria Quad**
(2022 formulation)

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- a) Only on a prescription
- b) No patient co-payment payable
- c)

A) INFLUENZA VACCINE – people 3 years and over

is available each year for patients aged 3 years and over who meet the following criteria, as set by Pharmac:

- a) all people 65 years of age and over; or
 - b) People 55 to 64 years of age (inclusive) and is Māori or any Pacific ethnicity; or
 - c) people under 65 years of age who:
 - i) have any of the following cardiovascular diseases:
 - a) ischaemic heart disease, or
 - b) congestive heart failure, or
 - c) rheumatic heart disease, or
 - d) congenital heart disease, or
 - e) cerebro-vascular disease; or
 - ii) have either of the following chronic respiratory diseases:
 - a) asthma, if on a regular preventative therapy, or
 - b) other chronic respiratory disease with impaired lung function; or
 - iii) have diabetes; or
 - iv) have chronic renal disease; or
 - v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
 - vi) have any of the following other conditions:
 - a) autoimmune disease, or
 - b) immune suppression or immune deficiency, or
 - c) HIV, or
 - d) transplant recipients, or
 - e) neuromuscular and CNS diseases/disorders, or
 - f) haemoglobinopathies, or
 - g) are children on long term aspirin, or
 - h) have a cochlear implant, or
 - i) errors of metabolism at risk of major metabolic decompensation, or
 - j) pre and post splenectomy, or
 - k) down syndrome, or
 - vii) are pregnant; or
 - d) children 3 and 4 years of age (inclusive) who have been hospitalised for respiratory illness or have a history of significant respiratory illness; or
 - e) people under 65 years of age who:
 - i) have any of the following serious mental health conditions:
 - a) schizophrenia, or
 - b) major depressive disorder, or
 - c) bipolar disorder, or
 - d) schizoaffective disorder, or
 - ii) are currently accessing secondary or tertiary mental health and addiction services; or
 - f) children 3 to 12 years of age (inclusive), from 1 July 2022 to 31 December 2022;
- Unless meeting the criteria set out above, the following conditions are excluded from funding:
- a) asthma not requiring regular preventative therapy,
 - b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Contractors will be entitled to claim payment for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with Health NZ for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
 - C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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MEASLES, MUMPS AND RUBELLA VACCINE

- Only on a prescription
- No patient co-payment payable
-

A) Measles, mumps and rubella vaccine

A maximum of two doses for any patient meeting the following criteria:

- For primary vaccination in children; or
- For revaccination following immunosuppression; or
- For any individual susceptible to measles, mumps or rubella; or
- A maximum of three doses for children who have had their first dose prior to 12 months.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes. Although a price is listed for the vaccine, doctors can still order measles mumps and rubella vaccine free of charge, as with other Schedule vaccines.

- Contractors will be entitled to claim payment for the supply of measles, mumps and rubella vaccine to patients eligible under the above criteria pursuant to their contract with Health NZ for subsidised immunisation, and they may only do so in respect of the measles, mumps and rubella vaccine listed in the Pharmaceutical Schedule.
- Contractors can only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Inj, measles virus 1,000 CCID50, mumps virus 5,012 CCID50,

Rubella virus 1,000 CCID50; prefilled syringe/ampoule of

diluent 0.5 ml	112.50	5	✓ MMR II
	250.00	10	✓ Priorix

MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJUGATE VACCINE – [Xpharm]

Either:

A) Any of the following:

- Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or
- One dose for close contacts of meningococcal cases of any group; or
- One dose for person who has previously had meningococcal disease of any group; or
- A maximum of two doses for bone marrow transplant patients; or
- A maximum of two doses for person pre- and post-immunosuppression*;

B) Both:

- Person is aged between 13 and 25 years, inclusive; and
- Either:
 - 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
 - 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 2021.

Note: 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.

Inj 4 mcg of each meningococcal polysaccharide conjugated to

a total of approximately 48 mcg of diphtheria toxoid carrier

per 0.5 ml vial	0.00	1	✓ Menactra
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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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MENINGOCOCCAL B MULTICOMPONENT VACCINE – [Xpharm]

Either:

A) Both:

- 1) Child is under one year of age; and
- 2) Any of the following:
 - i) up to three doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant; or
 - ii) up to three doses for close contacts of meningococcal cases of any group; or
 - iii) up to three doses for child who has previously had meningococcal disease of any group; or
 - iv) up to three doses for bone marrow transplant patients; or
 - v) up to three doses for child pre- and post-immunosuppression*;

B) Both:

- 1) Person is one year of age or over; and
- 2) Any of the following:
 - i) up to two doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant; or
 - ii) up to two doses for close contacts of meningococcal cases of any group; or
 - iii) up to two doses for person who has previously had meningococcal disease of any group; or
 - iv) up to two doses for bone marrow transplant patients; or
 - v) up to two doses for person pre- and post-immunosuppression*.

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

Inj 175 mcg per 0.5 ml prefilled syringe.....0.00 1 ✓ **Bexsero**

MENINGOCOCCAL C CONJUGATE VACCINE – [Xpharm]

Both:

- 1) The child is under 9 months of age; and
- 2) Any of the following:
 - 1) Up to three doses for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or
 - 2) Two doses for close contacts of meningococcal cases of any group; or
 - 3) Two doses for child who has previously had meningococcal disease of any group; or
 - 4) A maximum of two doses for bone marrow transplant patients; or
 - 5) A maximum of two doses for child pre- and post-immunosuppression*.

Note: children under nine months of age require two doses 8 weeks apart. Refer to the Immunisation Handbook for booster schedules with meningococcal ACWY vaccine.

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

Inj 10 mcg in 0.5 ml syringe.....0.00 1 ✓ **Neisvac-C**

PNEUMOCOCCAL (PCV10) CONJUGATE VACCINE – [Xpharm]

- 1) A primary course of three doses for previously unvaccinated individuals up to the age of 59 months inclusive

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

Inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B,

7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml

prefilled syringe0.00 10 ✓ **Synflorix**

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE – [Xpharm]

Any of the following:

- 1) Two doses are funded for high risk children (over the age of 12 months and under 18 years) who have previously received two doses of the primary course of PCV10; or
- 2) Up to an additional four doses (as appropriate) are funded for high risk children aged under 5 years for (re-)immunisation of patients with any of the following:
 - a) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
 - b) with primary immune deficiencies; or
 - c) with HIV infection; or
 - d) with renal failure, or nephrotic syndrome; or
 - e) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
 - f) with cochlear implants or intracranial shunts; or
 - g) with cerebrospinal fluid leaks; or
 - h) receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
 - i) with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
 - j) pre term infants, born before 28 weeks gestation; or
 - k) with cardiac disease, with cyanosis or failure; or
 - l) with diabetes; or
 - m) with Down syndrome; or
 - n) who are pre-or post-splenectomy, or with functional asplenia; or
- 3) Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients 5 years and over with HIV, for patients pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, intracranial shunts, cerebrospinal fluid leaks or primary immunodeficiency; or
- 4) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

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

Inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4,

5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5ml

syringe	0.00	10	✓ Prevenar 13
		1	✓ Prevenar 13

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE – [Xpharm]			
Either:			
1) Up to three doses (as appropriate) for patients with HIV, for patients post haematopoietic stem cell transplant, or chemotherapy; pre- or post-splenectomy or with functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or			
2) All of the following:			
a) Patient is a child under 18 years for (re-)immunisation; and			
b) Treatment is for a maximum of two doses; and			
c) Any of the following:			
i) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or			
ii) with primary immune deficiencies; or			
iii) with HIV infection; or			
iv) with renal failure, or nephrotic syndrome; or			
v) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or			
vi) with cochlear implants or intracranial shunts; or			
vii) with cerebrospinal fluid leaks; or			
viii) receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or			
ix) with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or			
x) pre term infants, born before 28 weeks gestation; or			
xi) with cardiac disease, with cyanosis or failure; or			
xii) with diabetes; or			
xiii) with Down syndrome; or			
xiv) who are pre- or post-splenectomy, or with functional asplenia.			
Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	0.00	1	✓ <u>Pneumovax 23</u>
POLIOMYELITIS VACCINE – [Xpharm]			
Up to three doses for patients meeting either of the following:			
1) For partially vaccinated or previously unvaccinated individuals; or			
2) For revaccination following immunosuppression.			
Note: Please refer to the Immunisation Handbook for appropriate schedule for catch-up programmes.			
Inj 80D antigen units in 0.5 ml syringe.....	0.00	1	✓ <u>IPOL</u>
ROTAVIRUS ORAL VACCINE – [Xpharm]			
Maximum of two doses for patients meeting the following:			
1) first dose to be administered in infants aged under 14 weeks of age; and			
2) no vaccination being administered to children aged 24 weeks or over.			
Oral susp live attenuated human rotavirus			
1,000,000 CCID50 per dose, prefilled oral applicator.....	0.00	10	✓ <u>Rotarix</u>

NATIONAL IMMUNISATION SCHEDULE

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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VARICELLA VACCINE [CHICKENPOX VACCINE] – [Xpharm]

Either:

- 1) Maximum of one dose for primary vaccination for either:
 - a) Any infant born on or after 1 April 2016; or
 - b) For previously unvaccinated children turning 11 years old on or after 1 July 2017, who have not previously had a varicella infection (chickenpox), or
- 2) Maximum of two doses for any of the following:
 - a) Any of the following for non-immune patients:
 - i) with chronic liver disease who may in future be candidates for transplantation; or
 - ii) with deteriorating renal function before transplantation; or
 - iii) prior to solid organ transplant; or
 - iv) prior to any elective immunosuppression*, or
 - v) for post exposure prophylaxis who are immune competent inpatients.; or
 - b) For patients at least 2 years after bone marrow transplantation, on advice of their specialist, or
 - c) For patients at least 6 months after completion of chemotherapy, on advice of their specialist, or
 - d) For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist, or
 - e) For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella, or
 - f) For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella, or
 - g) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

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

Inj 1350 PFU prefilled syringe	0.00	1	✓ Varivax
		10	✓ Varivax

VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] – [Xpharm]

Funded for patients meeting the following criteria:

- 1) Two doses for all people aged 65 years

Inj 50 mcg per 0.5 ml vial plus vial.....	0.00	1	✓ Shingrix
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VARICELLA ZOSTER VIRUS (OKA STRAIN) LIVE ATTENUATED VACCINE [SHINGLES VACCINE] – [Xpharm]

Funded for patients meeting the following criteria:

- 1) One dose for all people aged 65 years

Inj 19,400 PFU prefilled syringe plus vial	0.00	1	✓ Zostavax
		10	✓ Zostavax

Diagnostic Agents

TUBERCULIN PPD [MANTOUX] TEST – [Xpharm]

Inj 5 TU per 0.1 ml, 1 ml vial.....	0.00	1	✓ Tubersol
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