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Circulation

Accessible in an electronic format at no cost from the Pharmac website www.pharmac.govt.nz/schedule.

You can register to have an electronic version of the Pharmaceutical Schedule (link to PDF copy) emailed to your nominated email address each month by subscribing at pharmac.govt.nz/subscribe.

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Introducing Pharmac

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. The funding for pharmaceuticals comes from District Health Boards.

Pharmac's role:

"Secure for eligible people in need of pharmaceuticals, the best health outcomes that can reasonably be achieved, and from within the amount of funding provided."

New Zealand Public Health and Disability Act 2000

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 DHB Hospitals, as well as any access conditions that may apply; and
- the Pharmaceuticals, including Medical Devices, used in DHB 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 DHB 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 DHB 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 DHB hospitals. Section H lists the Pharmaceuticals that that can be used in DHB hospitals and is a separate publication.

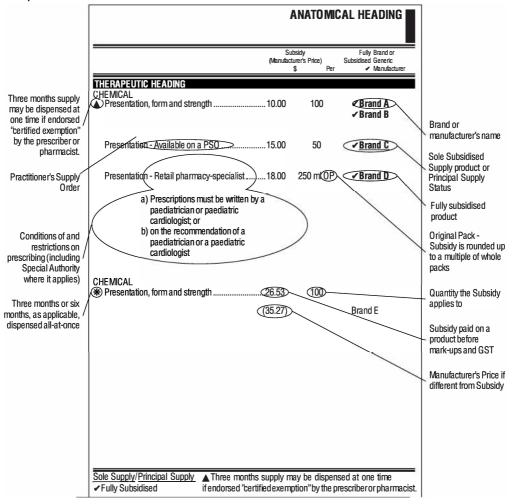
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

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



Glossary

Units of Measure

gramg kilogramkg international unitiu	mi mi mi
Abbreviations	
AmpouleAmp	Ge
CapsuleCap	Gr
Cream	Inf
DeviceDev	Ini
DispersibleDisp	Lic
EffervescentEff	Lo
EmulsionEmul	Oi
Enteric Coated EC	Sa

microgrammilligrammillilitre	mg
Gelatinous	
Granules	
Infusion	Inf
Injection	Inj
Liquid	Liq
Long Acting	LA
Ointment	Oint
Sachet	Sach

millimoleunit	
Solution	Supp Tab
Trans Dermal Delivery System	TDDS

Read the <u>General Rules</u>: <u>https://www.pharmac.govt.nz/section-a</u>.

SECTION B: ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price \$) Sul Per	Fully osidised	Brand or Generic Manufacturer
Antacids and Antiflatulents				
Antacids and Reflux Barrier Agents				
ALGINIC ACID Sodium alginate 225 mg and magnesium alginate 87.5 mg sachet	•	30	√ G	aviscon Infant
SODIUM ALGINATE * Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour		60	G	aviscon Double Strength
Oral liq 500 mg with sodium bicarbonate 267 mg and calcicarbonate 160 mg per 10 ml		500 ml	А	cidex
Phosphate Binding Agents				
ALUMINIUM HYDROXIDE * Tab 600 mg CALCIUM CARBONATE	12.56	100	✓ A	.lu-Tab
Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) — Subsidy by endorsement Only when prescribed for patients unable to swallow c inappropriate and the prescription is endorsed accordi	alcium carbonate table	500 ml ets or whe		loxane m carbonate tablets are
Antidiarrhoeals				
Agents Which Reduce Motility				
LOPERAMIDE HYDROCHLORIDE - Up to 30 cap available o * Tab 2 mg* * Cap 2 mg	10.75	400 400		lodia liamide Relief
Rectal and Colonic Anti-inflammatories				
BUDESONIDE Cap 3 mg - Special Authority see SA1886 below - Retail pharmacy SA1886 Special Authority for Subsidy nitial application — (Crohn's disease) from any relevant profits following criteria: 3oth:		90 valid for 6		intocort CIR or applications meeting

continued...

2 Any of the following:2.1 Diabetes; or2.2 Cushingoid habitus; or

1 Mild to moderate ileal, ileocaecal or proximal Crohn's disease; and

2.3 Osteoporosis where there is significant risk of fracture; or

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

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 allogenic 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 S29✓ Colifoam
HYDROCORTISONE ACETATE WITH PRAMOXINE HYDROCHLORIDE		
Topical aerosol foam, 1% with pramoxine hydrochloride 1%26.55	10 g OP	✓ Proctofoam S29
MESALAZINE		
Tab 400 mg49.50	100	✓ Asacol
Tab long-acting 500 mg56.10	100	✓ Pentasa
Tab 800 mg85.50	90	✓ Asacol
Modified release granules, 1 g118.10	100 OP	✓ Pentasa
Enema 1 g per 100 ml41.30	7	✓ Pentasa
Suppos 500 mg22.80	20	✓ Asacol
Suppos 1 g50.96	28	✓ Pentasa
OLSALAZINE		
Tab 500 mg93.37	100	Dipentum
Cap 250 mg53.00	100	✓ Dipentum

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
PREDNISOLONE SODIUM				
Rectal foam 20 mg per dose (14 applications)	74.10	1 OP	✓	Essential Prednisolone S29
SODIUM CROMOGLICATE Cap 100 mg	92.91	100	✓	Nalcrom
SULFASALAZINE	44.00	400		
* Tab 500 mg Tab EC 500 mg		100 100		Salazopyrin 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 g11.06	30 g OP	✓ Ultraproct
Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and cinchocaine hydrochloride 1 mg7.30	12	✓ Ultraproct
HYDROCORTISONE WITH CINCHOCAINE Oint 5 mg with cinchocaine hydrochloride 5 mg per g15.00 Suppos 5 mg with cinchocaine hydrochloride 5 mg per g9.90	30 g OP 12	✓ Proctosedyl ✓ Proctosedyl

Management of Anal Fissures

⇒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		5	✓ Buscopan
MEBEVERINE HYDROCHLORIDE			
* Tab 135 mg	9.20	90	✓ Colofac

Antiulcerants

Antisecretory and Cytoprotective

MIS	SOPROSTOL STORE ST		
*	Tab 200 mcg - Up to 120 tab available on a PSO41.50	120	Cytotec

		ALIMENTARY	TRAC	Γ AND	METABOLISM
		Subsidy (Manufacturer's Price) \$	Subs Per	Fully sidised	Brand or Generic Manufacturer
Н	elicobacter Pylori Eradication				
CL	ARITHROMYCIN Tab 500 mg — Subsidy by endorsement	adication and prescri		ndorsed	
Н	2 Antagonists				
	MOTIDINE – Only on a prescription Tab 20 mg	4.91	100	√ F	amotidine Hovid S29
*	Tab 40 mg	8.48	100	√ F	amotidine Hovid §29
*	Inj 10 mg per ml, 4 ml — Subsidy by endorsement		10 of palliati		lylan S29
P	roton Pump Inhibitors				
* * OM	NSOPRAZOLE Cap 15 mg Cap 30 mg IEPRAZOLE For omeprazole suspension refer Standard Formulae, page 2	5.26	100 100	√ <u>L</u>	anzol Relief anzol Relief
	Cap 10 mg		90		meprazole actavis
*	Cap 20 mg		90		meprazole actavis 20
*	Cap 40 mg	3.11	90	√ <u>0</u>	meprazole actavis 40
*	Powder – Only in combination Only in extemporaneously compounded omeprazole sus		5 g	✓ N	lidwest
*	Inj 40 mg ampoule with diluent		5	✓ <u>D</u>	r Reddy's Omeprazole
*	NTOPRAZOLE Tab EC 20 mg Tab EC 40 mg		100 100		anzop Relief anzop Relief
S	ite Protective Agents				
CC	LLOIDAL BISMUTH SUBCITRATE Tab 120 mg	14.51	50	√ G	astrodenol S29
SU	CRALFATE Tab 1 g	35.50	120	~	arafata

Bile and Liver Therapy

(48.28)

Carafate

Subsi	idv	Fully	Brand or
(Manufacture	,	Subsidised	
, φ	Dor	./	Manufacturar

⇒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

Hyperglycae	emic Aaents
-------------	-------------

DIAZOXIDE - Special Authority see SA1320 below -	- Retail pharmacy		
Cap 25 mg	110.00	100	✓ Proglicem S29
Cap 100 mg	280.00	100	✓ Proglicem S29
Oral liq 50 mg per ml	620.00	30 ml OP	✓ Proglycem S29

⇒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 PSO32.00	1	Glucagen Hypokit
--	---	------------------

Insulin - Short-acting Preparations

INS	SULIN NEUTRAL			
\blacktriangle	Inj human 100 u per ml	25.26	10 ml OP	Actrapid
	lai human 100 u nay ml. 2 ml	40.66	F	✓ Humulin R
_	Inj human 100 u per ml, 3 ml	42.00	5	 ✓ Actrapid Penfill ✓ Humulin R

Insulin - Intermediate-acting Preparations

▲ 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
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

	Subsidy (Manufacturer's Price	e) Subs	Fully idised	Brand or Generic
	\$	Per	1	Manufacturer
NSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
Inj lispro 25% with insulin lispro protamine 75% 100 u per ml,	,			
3 ml		5	✓	Humalog Mix 25
Inj lispro 50% with insulin lispro protamine 50% 100 u per ml,	ı		_	
3 ml	42.66	5	✓	Humalog Mix 50
Insulin - Long-acting Preparations				
NSULIN GLARGINE				
Inj 100 u per ml, 10 ml	63.00	1	✓	Lantus
Inj 100 u per ml, 3 ml		5	✓	Lantus
Inj 100 u per ml, 3 ml disposable pen	94.50	5	✓	Lantus SoloStar
Insulin - Rapid Acting Preparations				
NSULIN ASPART				
Inj 100 u per ml, 10 ml	30.03	1	✓	NovoRapid
Inj 100 u per ml, 3 ml		5		NovoRapid Penfill
Inj 100 u per ml, 3 ml syringe		5	✓	NovoRapid FlexPen
NSULIN GLULISINE				
Inj 100 u per ml, 10 ml	27.03	1	1	Apidra
Inj 100 u per ml, 3 ml	46.07	5	1	Apidra
Inj 100 u per ml, 3 ml disposable pen	46.07	5		Apidra SoloStar
NSULIN LISPRO				
Inj 100 u per ml, 10 ml		10 ml OP	✓	Humalog
Inj 100 u per ml, 3 ml	59.52	5	√	Humalog
Alpha Glucosidase Inhibitors				
CARBOSE				
★ Tab 50 mg	8.95	90	1	Accarb
₭ Tab 100 mg	15.29	90	√	<u>Accarb</u>
Oral Hypoglycaemic Agents				
GLIBENCLAMIDE				
₹ Tab 5 mg	7.50	100	✓	Daonil
GLICLAZIDE			-	
₹ Tab 80 mg	15.18	500	1	Glizide
GLIPIZIDE	- · · · ·	*	-	
₭ Tab 5 mg	4.58	100	✓ I	Minidiab
METFORMIN HYDROCHLORIDE				
F Tab immediate-release 500 mg	14 74	1.000	√ 1	Metformin Mylan
★ Tab immediate-release 500 mg		500		Metformin Mylan
PIOGLITAZONE				
Tab 15 mg	6.80	90	1	Vexazone
· · · · · · · · · · · · · · · · · · ·		90	1	Vexazone Vexazone
€ Tab 30 mg				
≮ Tab 30 mg ≮ Tab 45 mg	12.25	90		Vexazone
· · · · · · · · · · · · · · · · · · ·	12.25	90		Vexazone

[▲]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
VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE Tab 50 mg with 1,000 mg metformin hydrochloride Tab 50 mg with 850 mg metformin hydrochloride		60 60	-	Galvumet 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.

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:

- 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

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

continued...

- 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.

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

Dual Blood Glucose and Blood Ketone Testing

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

- a) Maximum of 1 pack per prescription
- b) Up to 1 pack available on a PSO
- c) A dual blood glucose and blood ketone diagnostic test meter is subsidised for a patient who has:
 - 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. 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

Blood Glucose Testing

BLOOD GLUCOSE DIAGNOSTIC TEST METER - Subsidy by endorsement

- a) Maximum of 1 pack per prescription
- b) Up to 1 pack available on a PSO
- c) A diagnostic blood glucose test meter is subsidised for a patient who:
 - 1) is receiving insulin or sulphonylurea therapy; or
 - 2) is pregnant with diabetes; or
 - 3) 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:

- 1) type 1 diabetes; or
- 2) permanent neonatal diabetes; or
- 3) undergone a pancreatectomy; or
- 4) 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

rips.......10.00 1 OP ✓ <u>CareSens N</u>

✓ CareSens N POP

20.00 ✓ CareSens N Premier

Note: Only 1 meter available per PSO

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
, , , , , , , , , , , , , , , , , , , ,	Per 🗸	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
- 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	50 test OP	•	CareSens N
		1	CareSens PRO

BLOOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)

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

- 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
- 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	.20 50 te	st 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 × 12.7 mm10.95	100	✓ B-D Micro-Fine
	31 g × 5 mm12.26	100	✓ B-D Micro-Fine
	31 g × 6 mm9.50	100	✓ Berpu
	31 g × 8 mm	100	✓ B-D Micro-Fine
	32 g x 4 mm 10.95	100	✓ B-D Micro-Fine

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

- a) Maximum of 1 dev per prescription
- b) Only on a prescription
- c) 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:

- 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 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; and
- 2 Patient remains fully compliant and transition to MDI is considered inappropriate by the treating physician; and
- 3 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

Subsidy (Manufacturer's Price)	F Subsidi	ully	Brand or Generic	
	Per	•	Manufacturer	

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 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 Fither:
 - 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 Fither:
 - 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 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 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

Subsidy		Fully	Brand or
(Manufacturer's Price)	9	Subsidised	Generic
\$	Per	✓	Manufacturer

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 Fither:
 - 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 Fully Brand or (Manufacturer's Price) Subsidised Generic Per ✓ Manufacturer

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 Fither:
 - 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 Fither:
 - 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 Fither:
 - 3.1 Applicant is a relevant specialist; or

Subsidy		Fully	Brand or
(Manufacturer's Price)	9	Subsidised	Generic
\$	Per	✓	Manufacturer

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 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
 - 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

1 OP

✓ TruSteel

	Subsidy (Manufacturer's Price) \$	Subsid Per	Fully ised ✓	Brand or Generic Manufacturer
continued than 80 mmol/mol; and The patient's HbA1c has not deteriorated more than 5 mm The patient has not had an increase in severe unexplained Either: 4.1 Applicant is a relevant specialist; or 4.2 Applicant is a nurse practitioner working within their	d hypoglycaemic epis			ne; and
INSULIN PUMP CARTRIDGE — Special Authority see SA1985 or a) Maximum of 3 sets per prescription b) Only on a prescription c) Maximum of 13 packs of cartridge sets will be funded per Cartridge 300 U. t:lock × 10	year.	narmacy	✓ T	andem Cartridge
INSULIN PUMP INFUSION SET (STEEL CANNULA) – Special A a) Maximum of 3 sets per prescription b) Only on a prescription c) Maximum of 13 infusion sets will be funded per year.	Authority see SA1985		9 – Re	etail pharmacy
10 mm steel needle; 60 cm tubing × 10		1 OP 1 OP		liniMed Sure-T MMT-884A liniMed Sure-T
6 mm steel needle; 60 cm tubing × 10		1 OP	✓ M	MMT-886A liniMed Sure-T MMT-864A
6 mm steel needle; 80 cm tubing × 10		1 OP 1 OP		liniMed Sure-T MMT-866A liniMed Sure-T
8 mm steel needle; 80 cm tubing × 10		1 OP		MMT-874A liniMed Sure-T MMT-876A
6 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	√ S	ure-T MMT-863
8 mm steel needle; 29 G; manual insertion; 60 cm tubing x 10 with 10 needles; luer lock		1 OP	_	ure-T MMT-873
INSULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT 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		cial Authorii 1 OP		SA1985 on page 19 –
8 mm steel cannula; straight insertion; 80 cm line × 10 with 10 needles	130.00	1 OP	✓ T	ruSteel
10 needles	130.00	1 OP	✓ T	ruSteel

8 mm steel cannula; straight insertion; 60 cm line × 10 with

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer

\$ Per

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

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
6 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	MMT-384A ✓ MiniMed Quick-Set
6 mm teflon needle, 45 cm blue tubing × 10	130.00	1 OP	MMT-398A ✓ MiniMed Mio
6 mm teflon needle, 45 cm pink tubing × 10	130.00	1 OP	MMT-941A ✓ MiniMed Mio
6 mm teflon needle, 60 cm blue tubing × 10	130.00	1 OP	MMT-921A ✓ MiniMed Mio
6 mm teflon needle, 60 cm pink tubing × 10	130.00	1 OP	MMT-943A ✓ MiniMed Mio
6 mm teflon needle, 60 cm tubing × 10	130.00	1 OP	MMT-923A ✓ MiniMed Quick-Set
6 mm teflon needle, 80 cm blue tubing	130.00	1 OP	MMT-399A ✓ MiniMed Mio
6 mm teflon needle, 80 cm clear tubing × 10	130.00	1 OP	MMT-945A ✓ MiniMed Mio
6 mm teflon needle, 80 cm pink tubing × 10	130.00	1 OP	MMT-965A ✓ MiniMed Mio
6 mm teflon needle, 80 cm tubing × 10	130.00	1 OP	MMT-925A ✓ MiniMed Quick-Set
9 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	MMT-387A ✓ MiniMed Quick-Set
9 mm teflon needle, 60 cm tubing × 10	130.00	1 OP	MMT-396A ✓ MiniMed Quick-Set
9 mm teflon needle, 80 cm clear tubing × 10	130.00	1 OP	MMT-397A ✓ MiniMed Mio
9 mm teflon needle, 80 cm tubing × 10	130.00	1 OP	MMT-975A ✓ MiniMed Quick-Set
			MMT-386A

	Subsidy (Manufacturer's Price) \$) Sub Per	Fully osidised	Brand or Generic Manufacturer
INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE IN	ISERTION WITH IN	SERTION	DEVICE	E) - 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 c	:m			
line x 10 with 10 needles		1 OP	✓ Aı	utoSoft 30
13 mm teflon cannula; angle insertion; insertion device; 60 cn line x 10 with 10 needles		1 OP	✓ A	utoSoft 30
INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE IN	SERTION) - Spec	cial Author	ity see S/	A1985 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 × 10 with 10 needles; luer lock	120.00	1 OP	√ Si	ilhouette MMT-373
•		-		
INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGH see SA1985 on page 19 – Retail pharmacy	I INSERTION WITH	H INSEKI	ION DEV	/ICE) - Special Authority
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 × 10 with 10 needles	140.00	1 OP	✓ Aı	utoSoft 90
6 mm teflon cannula; straight insertion; insertion device; 60 cr				
line × 10 with 10 needles	140.00	1 OP	✓ Ai	utoSoft 90
9 mm teflon cannula; straight insertion; insertion device;	140.00	4 OD		
110 cm line × 10 with 10 needles		1 OP	♥ Al	utoSoft 90
9 mm teflon cannula; straight insertion; insertion device; 60 cr		1 OP	✓ A	utoSoft 90
INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGH				
Retail pharmacy	I INSERTION) - 3	ppeciai Au	Honly Se	e 3A 1905 on page 19 -
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 \times 10 with	h			
10 needles; luer lock		1 OP	✓ Q	uick-Set MMT-393
9 mm teflon cannula; straight insertion; 60 cm tubing x 10 with		4.00		
10 needles; luer lock		1 OP	₽ Q	uick-Set MMT-392
INSULIN PUMP RESERVOIR – Special Authority see SA1985 or	n page 19 – Retail p	harmacy		
A) Maximum of 3 sets per prescription				
b) Only on a prescriptionc) Maximum of 13 packs of reservoir sets will be funded per	voor			
10 x luer lock conversion cartridges 1.8 ml for Paradigm pum		1 OP	✓ Δ1	DR Cartridge 1.8
Cartridge for 5 and 7 series pump; 1.8 ml × 10		1 OP		iniMed
1 17				1.8 Reservoir
				MMT-326A
Cartridge for 7 series pump; 3.0 ml × 10	50.00	1 OP		iniMed
				3.0 Reservoir
				MMT-332A

Subsidy		Fully	Brand or
(Manufacturer's Price)	S	ubsidised	Generic
\$	Per	1	Manufacturer

Digestives Including Enzymes

Р	Δ	١	J	CI	R	F	Δ	Т	IC.	F	N	7	1	Λ	F

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
Creon 10000 to be Principal Supply on 1 June 2022			
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
Creon 25000 to be Principal Supply on 1 June 2022			
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
URSODEOXYCHOLIC ACID - Special Authority see SA1739 below -	Retail pharm	nacy	
Cap 250 mg	.32.95	100	✓ <u>Ursosan</u>

⇒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 1
 - 1 Patient at risk of veno-occlusive disease or has hepatic impairment and is undergoing conditioning treatment prior to allogenic 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

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

continued...

2 Liver function has not improved with modifying the TPN composition.

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	-forn	nina	Agents
- WIII		9	190110

Powder for oral soln	6.00	250 g OP	✓ Macro Organic Psyllium Husk
	12.20	500 a OP	✓ KonsvI-D

ISPAGHULA (PSYLLIUM) HUSK - Only on a prescription

MU	CILAGINOUS LAXATIVES WITH STIMULANTS					
*	Dry	6.02	500 g OP			
	•	(17.32)	Ü	Norm	acol Plus	
		2.41	200 g OP			
		()	•			

2.41	200 g OP	
(8.72)		No

OP	
	Normacol Plus

Faecal Softeners

DOCUSATE SODIUM – Only on a prescription		
* Tab 50 mg	100	✓ Coloxyl
* Tab 120 mg	100	✓ Coloxyl
DOCUSATE SODIUM WITH SENNOSIDES		
* Tab 50 mg with sennosides 8 mg 4 20	200	✓ Laxsol

•	ŭ
POLOXAMER -	- Only on a prescription
Not funded	for use in the ser

	Not funded for use in the ear.		
*	Oral drops 10%	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:

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

continued...

GLYCEROL

Both:

- 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

GETGENGE			
* Suppos 3.6 g - Only on a prescription	9.25	20	✓ PSM
LACTULOSE - Only on a prescription			
* Oral liq 10 g per 15 ml	3.33	500 ml	✓ <u>Laevolac</u>
MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BIO	CARBONATE AN	ID SODIUM C	CHLORIDE
Powder for oral soln 13.125 g with potassium chloride 46.6 m	g,		
sodium bicarbonate 178.5 mg and sodium chloride 350.7	mg6.70	30	✓ Molaxole
SODIUM ACID PHOSPHATE - Only on a prescription			
Enema 16% with sodium phosphate 8%	2.50	1	✓ Fleet Phosphate
			Enema
SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE	- Only on a pre	scription	
Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml,			
5 ml	29.98	50	✓ Micolette
Stimulant Laxatives			
BISACODYL - Only on a prescription			
* Tab 5 mg	5.80	200	✓ Pharmacy Health
v	5.99		✓ Lax-Tab
Pharmacy Health to be Principal Supply on 1 June 2022			
* Suppos 10 mg	3.69	10	✓ <u>Lax-Suppositories</u>
(Lax-Tab Tab 5 mg to be delisted 1 June 2022)			
SENNA - Only on a prescription			
* Tab, standardised	2.17	100	

⇒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

(8.21)

0.43

(2.06)

20

30 ml OP

Senokot

Senokot

✓ Dulcolax SP Drop

2 The patient would otherwise require a high-volume bowel cleansing preparation or hospital admission.

SODIUM PICOSULFATE - Special Authority see \$A2053 below - Retail pharmacy

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

Metabolic Disorder Agents

ALGLUCOSIDASE ALFA - Special Authority see SA1986 on	the next page - Retail	pharmacy	
Inj 50 mg vial	1,142.60	1	✓ Myozyme

Subsid	dy Fully	Brand or
(Manufacture	er's Price) Subsidised	Generic
\$	Per 🗸	Manufacturer

⇒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 FRT; 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.

OININE O STATE A SECRET OF A S

ARGININE - Special Authority see SA2042 below - Retail	pnarmacy		
Tab 1,000 mg	CBS	90	Clinicians
Cap 500 mg	CBS	50	✓ Solgar
Powder	CBS	400 a	✓ 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 pharma	су	
Powder for oral soln575.00	180 g OP	Cystadane

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Subsi	dised	Generic	
\$	Per	•	Manufacturer	

⇒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 - S	pecial 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

⇒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.

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

⇒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 assav 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

✓ Aldurazyme

⇒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 (mucopolysacchardosis 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.

⇒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 mgCBS 100
Cap 100 mgCBS 100
✓ Country Life
✓ Solgar

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

⇒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

⇒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 mlCBS

SODIUM BENZOATE – Special Authority see SA1599 below – Retail pharmacy

⇒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

100 ml

✓ Amzoate S29

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

⇒SA1880 Special Authority for Subsidy

Special Authority approved by the Gaucher Treatment Panel

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

The Co-ordinator, Gaucher Treatment Panel Phone: 04 460 4990 Pharmac PO Box 10 254 Facsimile: 04 916 7571

Wellington Email: gaucherpanel@pharmac.govt.nz

Completed application forms must be sent to the coordinator for the Gaucher Treatment Panel and will be considered by the Gaucher Treatment Panel at the next practicable opportunity.

Notification of the Gaucher Treatment Panel's decision will be sent to the patient, the applying clinician and the patient's GP (if specified).

Access Criteria

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

- 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 taliglucerase alfa or might be reasonably expected to compromise a response to therapy with taliglucerase alfa; and
- 3) 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), unless otherwise agreed by Pharmac; and
- 4) Supporting clinical information including test reports, MRI whole body STIR, haematological data, and other relevant investigations, are submitted to the Gaucher Panel for assessment; and
- 5) Any of the following:
- Patient has haematological complications such as haemoglobin less than 95 g/l, symptomatic anaemia, thrombocytopenia; at least two episodes of severely symptomatic splenic infarcts confirmed with imagery; or

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

continued...

- massive symptomatic splenomegaly; or
 - 2) Patient has skeletal complications such as acute bone crisis requiring hospitalisation or major pain management strategies; radiological MRI Evidence of incipient destruction of any major joint (e.g. hips or shoulder); spontaneous fractures or vertebral collapse; chronic bone pain not controlled by other pharmaceuticals; or
 - 3) Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease; or
 - Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease: or
 - 5) Patient is a child and has experienced growth failure with significant decrease in percentile linear growth over a 6-12 month period.

*Unapproved indication

Renewal from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- Patient has demonstrated a symptomatic improvement or no deterioration in the main symptom for which therapy was initiated; and
- 2) Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size; and
- Radiological (MRI) signs of bone activity performed at two years since initiation of treatment, and three 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 had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates; and
- Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
- 6) Patient is compliant 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), unless otherwise agreed by Pharmac; and
- Supporting clinical information including test reports, MRI whole body STIR, haematological data, and other relevant investigations are submitted to the Gaucher Panel for assessment as required.

Mouth and Throat

Agents Used in Mouth Ulceration

BENZYDAMINE HYDROCHLORIDE

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

	Subsidy (Manufacturer's P	rice) Subs Per	Fully Brand or idised Generic ✓ Manufacturer
TRIAMCINOLONE ACETONIDE Paste 0.1%	5.33	5 g OP	✓ Kenalog in Orabase
Oropharyngeal Anti-infectives			
AMPHOTERICIN B Lozenges 10 mg	5.86	20	✓ Fungilin
AICONAZOLE Oral gel 20 mg per g	4.74	40 g OP	✓ <u>Decozol</u>
IYSTATIN Oral liq 100,000 u per ml	1.76	24 ml OP	✓ <u>Nilstat</u>
Vitamins			
Vitamin B			
HYDROXOCOBALAMIN ★ Inj 1 mg per ml, 1 ml ampoule - Up to 6 inj available on a PS	601.89 2.84 3.15	3	✓ Vita-B12 ✓ Neo-B12 ✓ Hydroxocobalamin
PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription Tab 25 mg - No patient co-payment payable		90	Mercury Pharma ✓ Vitamin B6 25
Tab 50 mg		500	✓ Apo-Pyridoxine ✓ Pyridoxine multichem
THIAMINE HYDROCHLORIDE - Only on a prescription Tab 50 mg //ITAMIN B COMPLEX		100	✓ Max Health
* 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	9.90	500	✓ Cvite
Vitamin D			
ALFACALCIDOL * Cap 0.25 mcg * Cap 1 mcg * Oral drops 2 mcg per ml	87.98	100 100 20 ml OP	✓ One-Alpha ✓ One-Alpha ✓ One-Alpha
* Cap 0.25 mcg* * Cap 0.5 mcg		100 100	✓ <u>Calcitriol-AFT</u> ✓ <u>Calcitriol-AFT</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

ALIMENTARY TRACT AND METABOLISM				
	Subsidy (Manufacturer's Pri	ce) Sub	Fully sidised	Brand or Generic Manufacturer
COLECALCIFEROL * Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescri * Oral liq 188 mcg per ml (7,500 iu per ml)		12 4.8 ml OP	✓ <u>Vi</u>	
Multivitamin Preparations				
MULTIVITAMIN RENAL - Special Authority see SA1546 below ★ Cap		30	✓ CI	inicians Renal Vit
Initial application from any relevant practitioner. Approvals va the following criteria: Either:	alid without further re	enewal unles	s notified	I for applications meeting
 The patient has chronic kidney disease and is receiving The patient has chronic kidney disease grade 5, defined ml/min/1.73 m² body surface area (BSA). 		•	•	
MULTIVITAMINS – Special Authority see SA1036 below – Ret * Powder		200 g OP	√ Pa	aediatric Seravit
■ SA1036 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals validorn errors of metabolism. Renewal from any relevant practitioner. Approvals valid without approval for multivitamins.				·
VITAMINS * Tab (BPC cap strength)		1,000	✓ M	<u>vite</u>
* Cap (fat soluble vitamins A, D, E, K) – Special Authority se SA1720 below – Retail pharmacy		60	✓ Vi	tabdeck
■ SA1720 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals value the following criteria: Any of the following: 1 Patient has cystic fibrosis with pancreatic insufficiency; 2 Patient is an infant or child with liver disease or short gu 3 Patient has severe malabsorption syndrome.	or	enewal unles	s notified	I for applications meeting
Minerals				
Calcium				
CALCIUM CARBONATE * Tab 1.25 g (500 mg elemental) * Tab eff 1.25 g (500 mg elemental) – Subsidy by endorsem Subsidy by endorsement – Only when prescribed for p considered unsuitable.	nent54.60	250 76 5 years) who	✓ Ca	alci-Tab 500 acit ⁸²⁹ um carbonate oral liquid i
CALCIUM GLUCONATE * Inj 10%, 10 ml ampoule	32.00	10		ax Health - Hameln §29

✓ Max Health S29

20

64.00

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
CALCIUM LACTATE GLUCONATE WITH CALCIUM CARBONATE Tab eff 2.94 g with calcium carbonate 0.3 g (500 mg element				
- Subsidy by endorsement	52.00	20	/	Calcium-Sandoz Forte S29
	260.00	100	•	Calcium-Sandoz Forte \$29

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

Fluoride		
SODIUM FLUORIDE * Tab 1.1 mg (0.5 mg elemental)8.64	100	✓ PSM
lodine		
POTASSIUM IODATE * Tab 253 mcg (150 mcg elemental iodine)	90	✓ NeuroTabs
Iron		
FERROUS FUMARATE * Tab 200 mg (65 mg elemental)	100	✓ Ferro-tab
FERROUS FUMARATE WITH FOLIC ACID * Tab 310 mg (100 mg elemental) with folic acid 350 mcg	100	✓ Ferro-F-Tabs
* Tab long-acting 325 mg (105 mg elemental)	30 500 ml	✓ Ferrograd✓ Ferodan
IRON (AS FERRIC CARBOXYMALTOSE) – Special Authority see SA1840 below Inj 50 mg per ml, 10 ml vial	– Retail phari 1	macy ✓ 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:

(Man	Subsidy	Fully		Brand or
	ufacturer's Price)	Subsidised		Generic
<u> </u>	\$	Per	✓	Manufacturer

continued...

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

wagnesium	wagne	sium
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MAGNESIUM HYDROXIDE Suspension 8%33.60	355 ml	✓ Phillips Milk of Magnesia \$29
MAGNESIUM SULPHATE * Inj 2 mmol per ml, 5 ml ampoule25.53	10	✓ <u>Martindale</u>
Zinc		
ZINC SULPHATE		

ZINIC	CIII	DHATE

*	Cap 137.4 mg (50 mg elemental)	11.00	100	✓ Zincaps
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Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per ✓ Manufacturer

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

	Subsidy		Fully	Brand or
	(Manufacturer's Price))	Subsidised	Generic
	\$	Per	✓	Manufacturer
EPOETIN ALFA - Special Authority see SA1775 on the previous	us page – Retail phari	macy		
Wastage claimable		•		
Inj 1,000 iu in 0.5 ml, syringe	250.00	6	✓ B	Sinocrit
Inj 2,000 iu in 1 ml, syringe		6	✓ B	Sinocrit
Inj 3,000 iu in 0.3 ml, syringe	150.00	6	✓ B	Sinocrit
Inj 4,000 iu in 0.4 ml, syringe	96.50	6	✓ B	Sinocrit
Inj 5,000 iu in 0.5 ml, syringe		6	✓ B	Sinocrit
Inj 6,000 iu in 0.6 ml, syringe	145.00	6	√ B	Sinocrit
Inj 8,000 iu in 0.8 ml, syringe	175.00	6	✓ B	Sinocrit
Inj 10,000 iu in 1 ml, syringe		6	√ <u>B</u>	<u>Sinocrit</u>
Inj 40,000 iu in 1 ml, syringe		1	✓ <u>B</u>	inocrit
Megaloblastic				
megalobiastio				
FOLIC ACID				
Tab 0.8 mg	21.84	1,000	✓ A	po-Folic Acid
v	26.60		√ F	olic Acid multichem
* Tab 5 mg	5.82	100	√ F	olic Acid Mylan
Oral liq 50 mcg per ml		25 ml O	_	liomed

Antifibrinolytics, Haemostatics and Local Sclerosants

EFTRENONACOG ALFA [RECOMBINANT FACTOR IX] - [Xpharm]

(Apo-Folic Acid Tab 0.8 mg to be delisted 1 May 2022)

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

ELTROMBOPAG – Special Authority see SA1743 below – Retail pharmacy Wastage claimable

⇒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.

	Subsidy		Fully	Brand or
(Ma	anufacturer's Price)	Subs	idised	Generic
	\$	Per	1	Manufacturer

continued...

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

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 Fither:
 - 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 Fither:
 - 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

✓ Hemlibra	1	3,570.00	Inj 30 mg in 1 ml vial
✓ Hemlibra	1	7,138.00	Inj 60 mg in 0.4 ml vial
✓ Hemlibra	1		Inj 105 mg in 0.7 ml vial
✓ Hemlibra	1	· · · · · · · · · · · · · · · · · · ·	Ini 150 mg in 1 ml vial

⇒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:

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

continued...

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

cabject to criteria.			
Inj 250 iu prefilled syringe	287.50	1	Xyntha
Inj 500 iu prefilled syringe		1	Xyntha
Inj 1,000 iu prefilled syringe		1	✓ Xyntha
Inj 2,000 iu prefilled syringe		1	Xyntha
Inj 3,000 iu prefilled syringe	3,450.00	1	✓ Xyntha

		NINING ONGANS		
	Subsidy (Manufacturer's Price)		Fully Subsidised	
	\$	Per	1	Manufacturer
NONACOG GAMMA, [RECOMBINANT FACTOR IX] - [Xpharn	า]			
For patients with haemophilia. Access to funded treatment with the National Haemophilia Management Group.	is managed by the Ha	emop	hilia Treat	ters Group in conjunction
Inj 500 iu vial	435.00	1	/	RIXUBIS
Inj 1,000 iu vial	870.00	1	1	RIXUBIS
Inj 2,000 iu vial	1,740.00	1	✓	RIXUBIS
Inj 3,000 iu vial		1	/	RIXUBIS
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE) -				
For patients with haemophilia. Preferred Brand of short hal				
managed by the Haemophilia Treaters Group in conjunction				
Inj 250 iu vial		1		Advate
Inj 500 iu vial		1		Advate
Inj 1,000 iu vial		1		Advate
Inj 1,500 iu vial	·	1	_	Advate
Inj 2,000 iu vial	·	1	_	Advate
Inj 3,000 iu vial	•	1	•	Advate
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENATE For patients with haemophilia. Rare Clinical Circumstances		e reco	ombinant f	actor VIII. Access to funded
treatment is managed by the Haemophilia Treaters Group in	n conjunction with the I	Vatio	nal Haemo	ophilia Management Group,
subject to criteria.	007.50		,	V
Inj 250 iu vial		1		Kogenate FS
Inj 500 iu vial		1		Kogenate FS
Inj 1,000 iu vial		1		Kogenate FS
Inj 2,000 iu vial Inj 3,000 iu vial		1		Kogenate FS
• •	•	ı	•	Kogenate FS
RURIOCTOCOG ALFA PEGOL [RECOMBINANT FACTOR VIII				
For patients with haemophilia A receiving prophylaxis treatment		d trea	atment is n	nanaged by the Haemophili
Treaters Group in conjunction with the National Haemophilic				
Inj 250 iu vial		1		Adynovate
Inj 500 iu vial		1		Adynovate
Inj 1,000 iu vial	•	1	_	Adynovate
Inj 2,000 iu vial	2,400.00	1	•	Adynovate
SODIUM TETRADECYL SULPHATE				
米 Inj 3% 2 ml	28.50	5		
	(73.00)			Fibro-vein
TRANEXAMIC ACID				
Tab 500 mg	9.45	60	1	Mercury Pharma
Vitamin K				
PHYTOMENADIONE	8.00	5	ı	Konakion MM
Inj 2 mg per 0.2 ml — Up to 5 inj available on a PSO				Konakion MM
Inj 10 mg per ml, 1 ml - Up to 5 inj available on a PSO		5		NOTICE IN
Antithrombotic Agents				
Antiplatelet Agents				
ASPIRIN				
* Tab 100 mg	10.80	990	1	Ethics Aspirin EC
Ť				

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
CLOPIDOGREL * Tab 75 mg	4.60	84	√ <u>C</u>	Clopidogrel Multichem
DIPYRIDAMOLE * Tab long-acting 150 mg		60	✓ <u>F</u>	ytazen SR
TICAGRELOR – Special Authority see SA1955 below – Retail pha * Tab 90 mg	•	56	✓ E	Brilinta

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 Fither:
 - 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

10

✓ Clexane Forte

 Subsidy acturer's Price) Subs	Fully sidised	Brand or Generic
 \$ Per	1	Manufacturer

continued...

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.

Heparin and Antagonist Preparations

ENOXAPARIN SODIUM - Special Authority see SA164	6 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		10	✓ Clexane
Inj 80 mg in 0.8 ml syringe		10	✓ Clexane
Inj 100 mg in 1 ml syringe		10	Clexane
Ini 120 mg in 0.8 ml syringe		10	✓ Clexane Forte

⇒SA1646 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.

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).

43

	Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic
	\$	Per	1	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 S29
	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		5	✓	Hospira
, ., , , .	42.40			Heparin DBL S29
	482.20	50		Heparin DBL S29
HEDADINICED CALINE	TOL.LO	00	•	i i opai iii oot
HEPARINISED SALINE	05.40	- 0	,	D#:
Inj 10 iu per ml, 5 ml		50	•	Pfizer
Oral Anticoagulants				
DABIGATRAN				
Cap 75 mg - No more than 2 cap per day	76.36	60	✓	Pradaxa
Cap 110 mg		60	✓	Pradaxa
Cap 150 mg		60	✓	Pradaxa
RIVAROXABAN				
Tab 10 mg - No more than 1 tab per day	83 10	30	1	Xarelto
Tab 15 mg — Up to 14 tab available on a PSO		28		Xarelto
Tab 20 mg		28		Xarelto
WARFARIN SODIUM		20	•	nui vito
Note: Marevan and Coumadin are not interchangeable. * Tab 1 mg	2.46	50	./	Coumadin
* Tab 1 mg	6.46	100		Coumadin Marevan
* Tab 2 mg	****	50		warevan Coumadin
* Tab 2 mg * Tab 3 mg		100		Coumadin Marevan
★ Tab 3 mg * Tab 5 mg		50		warevan Coumadin
1 1 au ⊃ iiiy	11.48	100		Coumadin Marevan
	11.40	100	•	IVIAI EVAII

FILGRASTIM - Special Authority see SA1259 below - Retail ph	armacy		
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 ×10⁹/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

✓ Neulastim 1

Subsidy (Manufacturer's Price)	Fı Subsidis	ully	Brand or Generic
\$	Per	✓	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
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 20	000 ml available on a PSO	1.23	500 ml	✓ Baxter
		1.26	1,000 ml	✓ Baxter
Only if prescribed o	n a prescription for renal dialysis	maternity or nost-nata	I care in the	home of the nationt

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
For Sodium chloride oral liquid formulation refer Standard	Formulae, page	e 242	
Inj 0.9%, 5 ml ampoule - Up to 5 inj available on a PSO	2.80	20	✓ Fresenius Kabi
Inj 0.9%, 10 ml ampoule - Up to 5 inj available on a PSO	5.40	50	✓ Fresenius Kabi
Inj 0.9%, 20 ml ampoule	5.00	20	✓ Fresenius Kabi
TOTAL PARENTERAL NUTRITION (TPN)			
Infusion	CBS	1 OP	✓ TPN

WATER

- 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

	Subsidy (Manufacturer's F		
	\$	Per	✓ 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	9.77	50	✓ Electral
COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE] Soln with electrolytes (2 × 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 (11.85)	60	Chlorvescent
* Tab long-acting 600 mg (8 mmol)		200	✓ Span-K
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

DC	DXAZOSIN			
*	Tab 2 mg	17.35	500	✓ Apo-Doxazosin✓ Doxazosin Clinect
*	Tab 4 mg	20.94	500	✓ Apo-Doxazosin ✓ Doxazosin Clinect
(A)	po-Doxazosin Tab 2 mg to be delisted 1 September 2022) po-Doxazosin Tab 4 mg to be delisted 1 September 2022) IENOXYBENZAMINE HYDROCHLORIDE			
*	Cap 10 mg	65.00	30	✓ BNM S29
	, ,	216.67	100	✓ Dibenzyline S29
PF	RAZOSIN			
*	Tab 1 mg	5.53	100	✓ Apo-Prazosin✓ Arrotex-PrazosinS29 S29
*	Tab 2 mg	7.00	100	 ✓ Apo-Prazosin ✓ Arrotex-Prazosin S29 S29
*	Tab 5 mg	11.70	100	 ✓ Apo-Prazosin ✓ Arrotex-Prazosin S29 S29

(Apo-Prazosin Tab 1 mg to be delisted 1 May 2022) (Apo-Prazosin Tab 2 mg to be delisted 1 May 2022)

(Apo-Prazosin Tab 5 mg to be delisted 1 May 2022)

Agents Affecting the Renin-Angiotensin System

ACE Inhibitors

0 4 DT 0 DD

CAPTOPRIL		
* Oral lig 5 mg per ml	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.

	dispensing of cilazapril.			
*	Tab 0.5 mg	2.09	90	✓ Zapril
*	Tab 2.5 mg		90	✓ Zapril
	Tab 5 mg	8.35	90	✓ Zapril
ΕN	ALAPRIL MALEATE			
*	Tab 5 mg	1.82	100	✓ Acetec
*	Tab 10 mg	2.02	100	✓ Acetec
	Tab 20 mg		100	✓ Acetec
LIS	SINOPRIL			
*	Tab 5 mg	17.50	90	 Ethics Lisinopril
*	Tab 10 mg	17.50	90	✓ Ethics Lisinopril
	Tab 20 mg		90	✓ Ethics Lisinopril

[▲]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	Generic
PERINDOPRIL Tab 2 mg Tab 4 mg QUINAPRIL Tab 5 mg Tab 10 mg Tab 20 mg ACE Inhibitors with Diuretics	2.95 5.97 5.18	30 30 90 90 90	<i>y</i>	Coversyl Coversyl Arrow-Quinapril 5 Arrow-Quinapril 10 Arrow-Quinapril 20
QUINAPRIL WITH HYDROCHLOROTHIAZIDE Tab 10 mg with hydrochlorothiazide 12.5 mg * Tab 20 mg with hydrochlorothiazide 12.5 mg		30 30		Accuretic 10 Accuretic 20
Angiotensin II Antagonists				
CANDESARTAN CILEXETIL * Tab 4 mg * Tab 8 mg * Tab 16 mg * Tab 32 mg COSARTAN POTASSIUM Tab 12.5 mg Tab 25 mg Tab 50 mg Tab 100 mg	2.28 3.31 5.26 1.56 1.84 2.25	90 90 90 90 84 84 84 84	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Candestar Candestar Candestar Candestar Candestar Losartan Actavis Losartan Actavis Losartan Actavis
Angiotensin II Antagonists with Diuretics				
OSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE Tab 50 mg with hydrochlorothiazide 12.5 mg	15.25	30	•	Arrow-Losartan & Hydrochlorothiazide
Angiotensin II Antagonists with Neprilysin Inhib	oitors			

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

Sub:	•	Fully	Brand or
(Manufactu		sidised	Generic
\$	S Per	•	Manufacturer

continued...

- 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.

For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaesthetics, Local, p	age 118	
AMIODARONE HYDROCHLORIDE		
▲ Tab 100 mg	30	✓ Aratac
▲ Tab 200 mg5.25	30	✓ Aratac
Inj 50 mg per ml, 3 ml ampoule - Up to 10 inj available on a		
PSO16.37	10	✓ Max Health
ATROPINE SULPHATE		
* Inj 600 mcg per ml, 1 ml ampoule - Up to 5 inj available on a		
PSO15.09	10	✓ <u>Martindale</u>
DIGOXIN		
* Tab 62.5 mcg – Up to 30 tab available on a PSO	240	✓ <u>Lanoxin PG</u>
* Tab 250 mcg – Up to 30 tab available on a PSO	240	Lanoxin
* Oral liq 50 mcg per ml	60 ml	✓ Lanoxin✓ Lanoxin Paediatric
		Elixir S29
		✓ Lanoxin S29 S29
DIOODYDAMIDE DIOODIATE		Lanoxin 529 529
DISOPYRAMIDE PHOSPHATE A Cap 100 mg23.87	100	✓ Rythmodan
	100	• Hydiiilouali
FLECAINIDE ACETATE A Tab 50 mg19.95	60	✓ Flecainide BNM
▲ Cap long-acting 100 mg	90	✓ Flecainide BNM
2 Out to fig accuracy footing	00	Controlled
		Release Teva
▲ Cap long-acting 200 mg61.06	90	✓ Flecainide
		Controlled
		Release Teva
Inj 10 mg per ml, 15 ml ampoule100.00	5	✓ Tambocor
MEXILETINE HYDROCHLORIDE		
▲ Cap 150 mg162.00	100	✓ Teva S29
▲ Cap 250 mg202.00	100	✓ Teva S29
PROPAFENONE HYDROCHLORIDE		
▲ Tab 150 mg40.90	50	✓ Rytmonorm

Antihypotensives

MIDODRINE - Special Authority see SA1474 on the next	page – Retail pharmacy		
Tab 2.5 mg	53.00	100	Gutron
Tab 5 mg	79.00	100	Gutron

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

⇒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.

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

ATENOI OI

ATENOLOL			
* Tab 50 mg	9.33	500	✓ Mylan Atenolol
* Tab 100 mg	14.20	500	✓ Mylan Atenolol
* Oral liq 25 mg per 5 ml	21.25	300 ml OP	✓ Atenolol AFT
			S29 S29
	38.20		✓ Essential
	00.20		Generics \$29
	49.85		✓ Atenolol AFT
Restricted to children under 12 years of age.	49.00		▼ Ateriolol AFT
, ,			
BISOPROLOL FUMARATE			
* Tab 2.5 mg		90	✓ Bisoprolol Mylan
* Tab 5 mg		90	✓ Bisoprolol Mylan
* Tab 10 mg	3.62	90	✓ Bisoprolol Mylan
CARVEDILOL			
* Tab 6.25 mg	2.24	60	Carvedilol Sandoz
* Tab 12.5 mg	2.30	60	Carvedilol Sandoz
* Tab 25 mg	2.95	60	Carvedilol Sandoz
LABETALOL			
* Tab 100 mg	14.50	100	✓ Trandate
* Tab 200 mg		100	✓ Trandate
* Inj 5 mg per ml, 20 ml ampoule		5	
, 01	(88.60)		Trandate
* inj 5 mg per ml, 20 ml vial	42.29 [′]	1	
, 01	(48.20)		Alvogen S29
METOPROLOL SUCCINATE	(10.00)		9
* Tab long-acting 23.75 mg	1 //5	30	✓ Betaloc CR
* Tab long-acting 25.75 mg		30	✓ Betaloc CR
* Tab long-acting 47.5 mg		30	✓ Betaloc CR
* Tab long-acting 95 mg		30	✓ Betaloc CR
	4.21	30	• Detailor Cit
METOPROLOL TARTRATE	F 00	100	/ IDOA Matarasalal
Tab 50 mg		100	✓ IPCA-Metoprolol
Tab 100 mg		60	✓ IPCA-Metoprolol
* Tab long-acting 200 mg		28	✓ Slow-Lopresor
* Inj 1 mg per ml, 5 ml vial	26.50	5	Metoprolol IV Mylan
NADOLOL			
Tab 40 mg	19.19	100	✓ Nadolol BNM S29
Tab 80 mg	30.39	100	✓ Nadolol BNM S29

_					
		Subsidy		Fully	Brand or
		(Manufacturer's Price)		bsidised	Generic
_		<u></u>	Per		Manufacturer
PIN	NDOLOL – Subsidy by endorsement				
	Subsidy by endorsement - Subsidised for patients who were	taking pindolol prior	to 1 Aug	ust 2021	and the prescription is
	endorsed accordingly. Pharmacists may annotate the presci dispensing of pindolol.				
*	Tab 5 mg	13.22	100	1	Apo-Pindolol
*	Tab 10 mg		100	1	Apo-Pindolol
*	Tab 15 mg		100	1	Apo-Pindolol
(Ar	po-Pindolol Tab 5 mg to be delisted 1 May 2022)				
(Ar	po-Pindolol Tab 10 mg to be delisted 1 May 2022)				
٠,	po-Pindolol Tab 15 mg to be delisted 1 May 2022)				
PR	ROPRANOLOL				
	Tab 10 mg	7.04	100	✓ [Drofate
	Tab 40 mg		100	-	PCA-Propranolol
*	Cap long-acting 160 mg		100	1	Cardinol LA
*					
•	Retail pharmacy		500 ml	✓ F	Roxane-
	······································			•	Propranolol S29

⇒SA1327 Special Authority for Subsidy

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

- 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 arrthymias 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 arrthymias or congenital cardiac abnormalities.

SOTAL OL

*	Tab 80 mg	2.58	500	✓ Mylan
	Tab 160 mg10		100	Mylan

Calcium Channel Blockers

Dihydropyridine Calcium Channel Blockers

ΑM	ILODIPINE			
*	Tab 2.5 mg	.08	90	✓ Vasorex
*	Tab 5 mg).96	90	✓ Vasorex
*	Tab 10 mg	.19	90	✓ Vasorex
FΕ	LODIPINE			
*	Tab long-acting 2.5 mg	1.45	30	✓ Plendil ER
	Tab long-acting 5 mg		90	✓ Felo 5 ER
	Tab long-acting 10 mg		90	✓ Felo 10 ER

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
IIFEDIPINE				
* Tab long-acting 10 mg	18.80	56	•	Tensipine MR10 S29
* Tab long-acting 20 mg	9.12	50	✓	Mylan (12 hr release) \$29
	17.72	100	✓	Nyefax Retard
* Tab long-acting 30 mg	4.78	14	•	Mylan Italy (24 hr release) \$29
	34.10	100	•	Mylan (24 hr release) \$29
Fab long-acting 60 mg	52.81	100	✓	Mylan (24 hr release) \$29
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
ERHEXILINE MALEATE				
	62.90	100	✓	Pexsig
ERAPAMIL HYDROCHLORIDE				
Tab 40 mg	7 01	100	1	Isoptin
÷ Tab 80 mg		100		Isoptin
Tab long-acting 120 mg		100		Isoptin Retard \$29
r ab long-acting 120 mg	30.02	100		Isoptin SR
Tab long-acting 240 mg	15.12	30		Isoptin SR
Inj 2.5 mg per ml, 2 ml ampoule - Up to 5 inj available on a				•
PSO		5	•	Isoptin
Centrally-Acting Agents				
LONIDINE				
Patch 2.5 mg, 100 mcg per day - Only on a prescription	10.34	4	✓	<u>Mylan</u>
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
LONIDINE HYDROCHLORIDE				
- Tab 25 mcg	8.75	112	✓	Clonidine BNM
	36.50			Clonidine Teva
Tab 150 mcg		100		Catapres
Inj 150 mcg per ml, 1 ml ampoule		10		Medsurge
ETHYLDOPA				
	15 10	100	1	Methyldopa Mylan
₹ Tab 250 mg	52.85	500		Methyldopa Mylan
	J2.0J	500	•	meniyidopa mylali

S29 S29

		Subsidy		Fully	Brand or
		(Manufacturer's Price		Subsidised	Generic
_		\$	Per		Manufacturer
П	iuretics				
Ľ					
L	oop Diuretics				
BU	METANIDE				
*	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
FU	ROSEMIDE [FRUSEMIDE]				
	Tab 40 mg - Up to 30 tab available on a PSO	8.00	1,000	1	IPCA-Frusemide
*	Tab 500 mg	25.00	50		Urex Forte
		89.48		1	Furosemid-
					Ratiopharm S29
		100.00	400		
		169.96	100	•	Furosemid-
					Ratiopharm S29
*	Oral lig 10 mg per ml	11 20	30 ml O	p 🗸	Lasix
	Inj 10 mg per ml, 25 ml ampoule		6		Lasix
	Inj 10 mg per ml, 2 ml ampoule – Up to 5 inj available on a P		5		Furosemide-Baxter
Р	otassium Sparing Diuretics				
	•				
AM	ILORIDE HYDROCHLORIDE	00.40	05 0		Diamad
	Oral liq 1 mg per ml		25 ml O	Ρ 🗸	Biomed
ΕP	LERENONE - Special Authority see SA1728 below - Retail pl	•		_	
	Tab 25 mg	18.50	30	•	Inspra
	Inspra to be Principal Supply on 1 June 2022	05.00	00		Income
	Tab 50 mg	25.00	30	•	Inspra
	Inspra to be Principal Supply on 1 June 2022				
	SA1728 Special Authority for Subsidy	Luithaut fuuthau va	سرر امریزم	laaa natif	iad far applications masting
	ial application from any relevant practitioner. Approvals valid following criteria:	without further re	enewai un	iless notif	led for applications meeting
Bot	•				
БО	1 Patient has heart failure with ejection fraction less than 40°	%: and			
	2 Either:	/o, and			
	2.1 Patient is intolerant to optimal dosing of spironolact	one. or			
	2.2 Patient has experienced a clinically significant adve		n optimal	dosina o	f spironolactone.
	, ,				
IVI⊏	TOLAZONE	ODO		,	Matalagan
	Tab 5 mg	CBS	1		Metolazone S29
			50	•	Zaroxolyn S29
	RONOLACTONE				
	Tab 25 mg		100		Spiractin
*	Tab 100 mg		100		Spiractin
	Oral liq 5 mg per ml	30.60	25 ml O	۲ 🗸	Biomed
P	otassium Sparing Combination Diuretics				
7	otassium spanny combination biuretics				
ΑM	ILORIDE HYDROCHLORIDE WITH FUROSEMIDE				

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

53

✓ Frumil

28

* Tab 5 mg with furosemide 40 mg8.63

		Subsidy (Manufacturer's Pric \$	e) Pe	Fully Subsidised	
	ORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIAZIE ab 5 mg with hydrochlorothiazide 50 mg		50	•	Moduretic
Thi	azide and Related Diuretics				
	DROFLUMETHIAZIDE [BENDROFLUAZIDE] ab 2.5 mg - Up to 150 tab available on a PSO	20.00	500	•	Arrow- Bendrofluazide
k T	May be supplied on a PSO for reasons other than emerge ab 5 mg	•	500	•	Arrow- Bendrofluazide
C	OROTHIAZIDE Oral lig 50 mg per ml	27.82	25 ml	OP 🗸	Biomed
Т	DRTALIDONE [CHLORTHALIDONE] ab 25 mg	3.90 6.50	30 50	_	Igroton S29 Hygroton
	PAMIDE ab 2.5 mg	10.45 11.61	90 100		Dapa-Tabs Mylan Indapamide S29
Lip	id-Modifying Agents				
Fib	rates				
* T	AFIBRATE Tab 200 mg		90 30		Bezalip Bezalip Retard
Oth	ner Lipid-Modifying Agents				
	IMOX Cap 250 mg	21.56	30		Olbetam Olbetam S29 S29
Res	sins				
	ESTIPOL HYDROCHLORIDE Grans for oral liq 5 g	32.89	30	•	Colestid
НМ	G CoA Reductase Inhibitors (Statins)				
* T * T * T * T PRA\	RVASTATIN ab 10 mg ab 20 mg ab 40 mg ab 80 mg /ASTATIN	9.24 14.92 26.54	500 500 500 500	\(\)	Lorstat Lorstat Lorstat Lorstat
	ab 40 mgab 40 mg		28 28	_	<u>Pravastatin Mylan</u> <u>Pravastatin Mylan</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
ROSUVASTATIN - Special Authority see SA2093 below - Reta	il pharmacy				
Tab 5 mg	1.70	30	✓ F	Rosuvastatin Viatris	
Rosuvastatin Viatris to be Sole Supply on 1 May 2022					
Tab 10 mg	2.42	30	√ F	Rosuvastatin Viatris	
Rosuvastatin Viatris to be Sole Supply on 1 May 2022					
Tab 20 mg	3.92	30	√ F	Rosuvastatin Viatris	
Rosuvastatin Viatris to be Sole Supply on 1 May 2022					
Tab 40 mg	5.28	30	√ F	Rosuvastatin Viatris	
Rosuvastatin Viatris to be Sole Supply on 1 May 2022					

⇒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:

Fither:

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.

SIN	IVASTATIN		
*	Tab 10 mg	90	Simvastatin Mylan
*	Tab 20 mg	90	✓ Simvastatin Mylan
	Tab 40 mg		✓ Simvastatin Mylan
	Tab 80 mg7.12		✓ Simvastatin Mylan

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Subsid	dised	Generic	
\$	Per	/	Manufacturer	

Selective Cholesterol Absorption Inhibitors

⇒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 $10 \times \text{normal}$) 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		30	✓ Zimybe
Tab 10 mg with simvastatin 40 mg	7.15	30	✓ Zimybe
Tab 10 mg with simvastatin 80 mg		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.

_		Subsidy		Fully	Brand or
		(Manufacturer's		sidised	Generic
_		\$	Per	✓	Manufacturer
I.	litrates				
ľ	illiales				
GL	YCERYL TRINITRATE				
*	Oral pump spray, 400 mcg per dose - Up to 250 dose				
	available on a PSO	6.09	250 dose OP	✓ N	litrolingual Pump
					Spray
*	Patch 25 mg, 5 mg per day	15.73	30	✓ N	litroderm TTS
*	Patch 50 mg, 10 mg per day	18.62	30	✓ N	litroderm TTS
ISO	DSORBIDE MONONITRATE				
*	Tab 20 mg	19.55	100	✓ <u>I</u>	smo 20
*	Tab long-acting 40 mg	8.20	30	√ <u> </u>	smo 40 Retard
*	Tab long-acting 60 mg	9.25	90	✓ [<u>Ouride</u>
ક	ympathomimetics				
ΔΓ	RENALINE				
76	Inj 1 in 1,000, 1 ml ampoule - Up to 5 inj available on a PSC) 498	5	✓ 1	Aspen Adrenaline
	ing that 1,000, this ampound to plot of ing available on a too	10.76	Ŭ		BL Adrenaline
	Inj 1 in 10,000, 10 ml ampoule - Up to 5 inj available on a P	SO27.00	5	√ F	lospira
		49.00	10	√	Aspen Adrenaline
V	asodilators				
НУ	DRALAZINE HYDROCHLORIDE				
	Tab 25 mg - Special Authority see SA1321 below - Retail				
•••	pharmacy	CBS	1	✓	lydralazine
	F,		56		Onelink S29
			84		MDIPHARM \$29
			100	-	Onelink S29
*	Inj 20 mg ampoule	25.90	5		presoline
_	SA1321 Special Authority for Subsidy				
	tial application from any relevant practitioner. Approvals valid	d without furthe	r renewal unless	s notifie	d for applications meeting
	e following criteria:	a williout fartifo	i Tonowai amoo	7 11011110	a for applications meeting
	her:				
	1 For the treatment of refractory hypertension; or				
	2 For the treatment of heart failure in combination with a nitr	rate, in patients	who are intolera	ant or h	ave not responded to ACE
	inhibitors and/or angiotensin receptor blockers.				
MI	NOXIDIL				
\blacktriangle	Tab 10 mg	70.00	100	√ L	oniten.
NI	CORANDIL				
	Tab 10 mg	25.57	60	✓	korel
\blacktriangle	Tab 20 mg	32.28	60	✓	korel
PA	PAVERINE HYDROCHLORIDE				
	Inj 12 mg per ml, 10 ml ampoule	257.12	5	√ F	lospira
	NTOXIFYLLINE [OXPENTIFYLLINE]				•
	Tab 400 mg	42.26	50	✓ T	rental 400
		-		-	

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

Endothelin Receptor Antagonists

AMBRISENTAN - Special Authority see	SA1702 below – Retail pharmacy		
Tab 5 mg	1,550.00	30	 Ambrisentan Mylan
Tab 10 mg	1,550.00	30	✓ Ambrisentan Mylan
•			✓ Mylan

⇒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 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

⇒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 Fither:
 - 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:

	Subsidy	F	ully	Brand or
(Mar	ufacturer's Price)	Subsid	sed	Generic
	\$	Per	•	Manufacturer

continued...

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:
 - 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 NYHAWHO 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 SA 1992 below – Retail pharmacy
✓ Vedafil	4	Tab 25 mg
✓ Vedafil	4	Tab 50 mg1.70
✓ Vedafil	12	

⇒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

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

continued...

- 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
 - 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 (dvn 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 - Reta	il pharmacy		
Inj 500 mcg vial	36.61	1	✓ Veletri
Inj 1.5 mg vial	73.21	1	✓ Veletri

⇒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 ml740.10 30 ✓ Ventavis

⇒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

DERMATOLOGICALS

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

Antiacne Preparations

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 89

ADAPALENE

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

b) 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 - Ret	tail 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:

- 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 isotretinoin and is competent to prescribe isotretinoin; 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 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
 - 3.2 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:

Fither:

- 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 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
- 2 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.

TRFTINOIN

Crm 0.5 mg per q − Maximum of 50 g per prescription......15.57 50 g OP ✓ ReTrieve

Antibacterials Topical

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 89

HYDROGEN PEROXIDE

DERMATOLOGICALS

	Subsidy (Manufacturer's F	Price) Subs	Fully	Brand or Generic
	\$	Per	✓	Manufacturer
MUPIROCIN				
Oint 2%	6.60	15 g OP		
	(11.50)	Ü	В	actroban
a) Only on a prescription	, ,			
b) Not in combination				
SODIUM FUSIDATE [FUSIDIC ACID]				
Crm 2%	1 50	5 g OP	√ F	oban
a) Maximum of 5 g per prescription	1.55	3 9 01	• <u>-</u>	Oban
b) Only on a prescription				
c) Not in combination				
Oint 2%	1 50	5 g OP	√ F	oban
	1.00	3 9 01	• !	Oban
a) Maximum of 5 g per prescriptionb) Only on a prescription				
c) Not in combination				
,				
SULFADIAZINE SILVER				
Crm 1%	10.80	50 g OP	✓ F	lamazine
a) Up to 250 g available on a PSO				
b) Not in combination				
Antifungals Topical				
- · · · · · · · · · · · · · · · · · · ·	00			
For systemic antifungals, refer to INFECTIONS, Antifungals, p	page 96			
For systemic antifungals, refer to INFECTIONS, Antifungals, page 34 AMOROLFINE	page 96			
AMOROLFINE a) Only on a prescription	page 96			
AMOROLFINE a) Only on a prescription b) Not in combination				
AMOROLFINE a) Only on a prescription		5 ml OP	✓ <u>N</u>	lycoNail
AMOROLFINE a) Only on a prescription b) Not in combination		5 ml OP	✓ <u>N</u>	lycoNail
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%		5 ml OP	✓ <u>N</u>	lycoNail
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%		5 ml OP	✓ <u>N</u>	lycoNail
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	14.93	5 ml OP		
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	14.93			lycoNail .po-Ciclopirox
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	14.93			
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	14.93	7 ml OP	✓ A	po-Ciclopirox
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	14.93		✓ A	
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	14.93	7 ml OP	✓ A	po-Ciclopirox
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	5.72	7 ml OP 20 g OP	✓ A	po-Ciclopirox
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	5.72 0.77	7 ml OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	5.72	7 ml OP 20 g OP	✓ A	po-Ciclopirox
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	5.72 0.77	7 ml OP 20 g OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	5.72 0.77	7 ml OP 20 g OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	5.720.774.36 (7.55)	7 ml OP 20 g OP 20 ml OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	5.720.774.36 (7.55)	7 ml OP 20 g OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%	5.720.774.36 (7.55)	7 ml OP 20 g OP 20 ml OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP	✓ A	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP	✓ A ✓ C	po-Ciclopirox Clomazol
AMOROLFINE a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP	✓ A ✓ C	po-Ciclopirox Clomazol Canesten

	Subsidy (Manufacturer's F	Prico) Sub	Fully	Brand or Generic
	(Manufacturer's F	Per	siuiseu 🗸	Manufacturer
MICONAZOLE NITRATE				
* Crm 2%	0.81	15 g OP	✓ N	<u>flultichem</u>
a) Only on a prescription				
b) Not in combination				
* Lotn 2%		30 ml OP		
	(10.03)			Daktarin
a) Only on a prescription				
b) Not in combination				
* Tinct 2%		30 ml OP	_	
	(12.10)			Daktarin
a) Only on a prescription				
b) Not in combination				
Antipruritic Preparations				
Anapranao i reparadons				
CALAMINE				

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

Crm, aqueous, BP......1.08

....1.08 100 g

✓ Calamine-AFT

✓ healthE Calamine Aqueous Cream BP

Calamine-AFT to be Principal Supply on 1 May 2022

(healthE Calamine Aqueous Cream BP Crm, aqueous, BP to be delisted 1 May 2022)

CROTAMITON

a) Only on a prescription

b) Not in combination

20 g OP

✓ Itch-Soothe

MENTHOL - Only in combination

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

Crystals	
29.60	

25 g 100 g ✓ MidWest
✓ MidWest

Corticosteroids Topical

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 79

Corticosteroids - Plain

ΒE	TAMETHASONE 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
ВЕ	TAMETHASONE 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

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

	Subsidy		Fully	Brand or
	(Manufacturer's P		idised	Generic
	\$	Per		Manufacturer
CLOBETASOL PROPIONATE				
* Crm 0.05%		30 g OP	-	<u>Dermol</u>
* Oint 0.05%	2.12	30 g OP	✓ [<u>Dermol</u>
CLOBETASONE BUTYRATE				
Crm 0.05%		30 g OP		
	(10.00)		-	Eumovate
HYDROCORTISONE				
* Crm 1% - Only on a prescription	3.70	100 g OP	✓ [Hydrocortisone
				(PSM)
	17.15	500 g	✓ [Hydrocortisone
			_	(PSM)
* Powder – Only in combination		25 g	/	ABM
Up to 5% in a dermatological base (not proprietary To	opical Corticosteriod	- Plain) with o	or with	out other dermatological
galenicals				
HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLII				
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - On				
a prescription	10.57	250 ml	•	DP Lotn HC
HYDROCORTISONE BUTYRATE				
Lipocream 0.1%		100 g OP		Locoid Lipocream
Oint 0.1%		100 g OP		Locoid
Milky emul 0.1%	12.33	100 ml OP	•	Locoid Crelo
METHYLPREDNISOLONE ACEPONATE			_	
Crm 0.1%		15 g OP	-	Advantan
Oint 0.1%	4.46	15 g OP		<u>Advantan</u>
MOMETASONE FUROATE			_	
Crm 0.1%		15 g OP		Elocon Alcohol Free
01.10.40/	3.10	50 g OP		Elocon Alcohol Free
Oint 0.1%		15 g OP	-	Elocon
Lotn 0.1%	2.90	50 g OP 30 ml OP	-	<u>Elocon</u> Elocon
	4.50	30 IIII OP	• !	Elocon
TRIAMCINOLONE ACETONIDE	2.22	400 00		
Crm 0.02%		100 g OP		Aristocort Aristocort
OITI 0.02%	0.33	100 g OP		Aristocort
Corticosteroids - Combination				
Total Color Clare Collision Care Collision Care Care Care Care Care Care Care Care				
BETAMETHASONE VALERATE WITH SODIUM FUSIDATE				
Crm 0.1% with sodium fusidate (fusidic acid) 2%		15 g OP		
	(10.45)		ı	=ucicort
a) Maximum of 15 g per prescription				
b) Only on a prescription				
HYDROCORTISONE WITH MICONAZOLE - Only on a pres	cription			
* Crm 1% with miconazole nitrate 2%	1.89	15 g OP	✓ [Micreme H
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN	- Only on a prescrip	tion		
Crm 1% with natamycin 1% and neomycin sulphate 0.5%		15 g OP	✓ [Pimafucort
Oint 1% with natamycin 1% and neomycin sulphate 0.5%	3.35	15 g OP	√	Pimafucort
(Pimafucort Crm 1% with natamycin 1% and neomycin sulpha	nte 0.5% to be deliste	ed 1 May 2022)	

	Subsidy (Manufacturer's F	Price) Subsi Per	Fully Brand or idised Generic ✓ Manufacturer
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCI Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g - Only on a prescription	9	ГІN 15 g ОР	Viaderm KC
Barrier Creams and Emollients			
Barrier Creams			
DIMETHICONE			
* Crm 5% pump bottle	4.48	500 ml OP	✓ <u>healthE</u> Dimethicone 5%
* 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	✓ GEM Aqueous Cream
	1.92		✓ Basic AquaCream✓ Boucher
GEM Aqueous Cream to be Principal Supply on 1 April 2 (Basic AquaCream Crm to be delisted 1 April 2022) (Boucher Crm to be delisted 1 April 2022) (Medco Crm to be delisted 1 April 2022)	2022		✓ Medco
CETOMACROGOL	4.00	F00	/ O-t
* Crm BP Cetomacrogol-AFT to be Principal Supply on 1 May 202: (healthE Crm BP to be delisted 1 May 2022)	2.48	500 g	✓ Cetomacrogol-AFT ✓ healthE
CETOMACROGOL WITH GLYCEROL Crm 90% with glycerol 10%	2.25	500 ml OP	✓ Boucher
Gill 90 % with gryceror 10 %	2.33	300 IIII OF	✓ Pharmacy Health Sorbolene with Glycerin
EMULSIFYING OINTMENT	3.10	1,000 ml OP	✓ <u>Boucher</u>
* Oint BP	3.40	500 g	✓ Emulsifying Ointment ADE
OIL IN WATER EMULSION * Crm	2.19	500 g	✓ O/W Fatty Emulsion Cream
PARAFFIN Oint liquid paraffin 50% with white soft paraffin 50%	5.35	500 ml OP	✓ healthE
UREA	4.07	400 - 00	/ backbert.
* Crm 10%	1.3/	100 g OP	healthE Urea Cream

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

DERMATOLOGICALS

	Subsidy (Manufacturer's F	Price) Subsi	Fully idised	Brand or Generic Manufacturer
WOOL FAT WITH MINERAL OIL - Only on a prescription	-			
* Lotn hydrous 3% with mineral oil	5.60	1,000 ml		
•	(11.95)			OP Lotion
	` 1.40 [′]	250 ml OP		
	(4.53)			P Lotion
	5.60	1,000 ml		
	(20.53)		Α	Alpha-Keri Lotion
	(23.91)		В	K Lotion
	1.40	250 ml OP		
	(7.73)		В	BK Lotion

Other Dermatological Bases

PARAFFIN

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

Parasiticidal Preparations

DIN	1 □	ᇚ	\sim	JVI	ᆮ
יווט	VIL.		ıv	אוע	_

		Lotion
IVERMECTIN – Special Authority see SA1225 below – Retail pharmacy		
Tab 3 mg - Up to 100 tab available on a PSO17.20	4	✓ Stromectol

- 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.
- For the purposes of subsidy of ivermectin, institution means age related residential care facilities, disability care facilities or prisons.

⇒SA1225 Special Authority for Subsidy

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

continued...

200 ml OP

✓ healthE

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

continued...

Both:

- 1 Applying clinician has discussed the diagnosis of scabies with a dermatologist, infectious disease physician or clinical microbiologist; and
- 2 Fither:
 - 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 scables 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 — (Scables) 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



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

continued...

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.

PFRMFTHRIN

Crm 5%5.75	30 g OP	✓ Lyderm
Lotn 5%	30 ml OP	✓ A-Scables

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;
- 2 Patient is not of child bearing potential.

RETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL

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
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 Corticosteriod Plain
- 2) With or without other dermatological galenicals.

	Subsidy		Fully Brand or
	(Manufacturer's P \$	Per Subs	sidised Generic Manufacturer
COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SUL	PHUR		
Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% an			
allantoin crm 2.5%		75 g OP	
	(8.00)	Ü	Egopsoryl TA
	3.43	30 g OP	
	(4.35)		Egopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR			_
Soln 12% with salicylic acid 2% and sulphur 4% oint		25 g OP	✓ Coco-Scalp
	7.95	40 g OP	✓ Coco-Scalp
PIMECROLIMUS – Special Authority see SA1970 below – Reta	il pharmacy		
a) Maximum of 15 g per prescription			
b) Note: a maximum of 15 g per prescription and no more to			
Cream 1%	28.50	15 g OP	✓ <u>Elidel</u>
⇒SA1970 Special Authority for Subsidy	la a laca al a sel a la comunica		
Initial application only from a dermatologist, paediatrician, opht of a dermatologist, paediatrician or ophthalmologist. Approvals	naimologist or an	y relevant prac	ctitioner on the recommendation
meeting the following criteria:	zana without lurth	er renewai uni	ess notined for applications
Both:			
1 Patient has atopic dermatitis on the eyelid; and			
2 Patient has at least one of the following contraindications	to topical corticos	steroids: perio	orificial dermatitis, rosacea,
documented epidermal atrophy, documented allergy to to			
pressure.			
PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORE	SCEIN - Only or	n a prescription	n
* Soln 2.3% with trolamine laurilsulfate and fluorescein sodium	n4.44	500 ml	✓ Pinetarsol
SALICYLIC ACID			
Powder - Only in combination	18.88	250 g	✓ Midwest
			✓ PSM
 Only in combination with a dermatological base or 	proprietary Topic	al Corticostero	oid – Plain or collodion flexible
2) With or without other dermatological galenicals.			
(DOM Decodes to be delicated 4 May 2000)			
(PSM Powder to be delisted 1 May 2022)			
SULPHUR	0.05	400	4 1 1 1
Precipitated – Only in combination		100 g	✓ Midwest
Only in combination with a dermatological base or	proprietary Topic	al Corticostero	oid – Plain
2) With or without other dermatological galenicals.			
7.070.000			
TACROLIMUS			
Oint 0.1% - Special Authority see SA2074 below - Retail	00.00	00 × 0D	4.7
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 m 	ore than one pro-	ecription per 1) wooke
b) Note. a maximum of 30 g per prescription and no m	ore than one pres	onpuon per 12	- WOONS.
PORCHA SOCIAL AUTODITY FOR SUDSIGN			

⇒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.

DERMATOLOGICALS

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

Scalp Preparations

BETAMETHASONE VALERATE			42.4
* Scalp app 0.1% CLOBETASOL PROPIONATE	9.84	100 ml OP	✓ Beta Scalp
* Scalp app 0.05%	5.69	30 ml OP	✓ <u>Dermol</u>
HYDROCORTISONE BUTYRATE Scalp lotn 0.1%	6 57	100 ml OP	✓ Locoid
KETOCONAZOLE	0.57	100 1111 01	Locolu
Shampoo 2%	3.23	100 ml OP	✓ <u>Sebizole</u> ✓ Sebizole

- 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.

Wart Preparations

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 68

IMIQUIMOD

Crm 5%, 250 mg sachet.....21.72

24

✓ Perrigo

PODOPHYLLOTOXIN

b) Only on a prescription

3.60 3.5 ml OP

✓ Condyline

Other Skin Preparations

Antineoplastics

FLUOROURACIL SODIUM

GENITO-URINARY SYSTEM

Sub	bsidy	Fully Brand or
(Manufactu	turer's Price) Subsic	lised Generic
•	\$ Per	 Manufacturer

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

Contraceptives - Non-hormonal

Condoms

ONDOMS			
€ 49 mm - Up to 144 dev available on a PSO		144	✓ Moments
÷ 53 mm	0.95	10	✓ Moments
	11.64	144	✓ Moments
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	✓ Moments
•	11.42	144	✓ Moments
a) Up to 60 dev available on a PSO			
b) Maximum of 60 dev per prescription			
53 mm, chocolate, brown	0.95	10	✓ Moments
,,,	11.64	144	✓ Moments
a) Up to 60 dev available on a PSO			
b) Maximum of 60 dev per prescription			
53 mm, strawberry, red	0.95	10	✓ Moments
55, olanson, j, roalii	11.64	144	✓ Moments
a) Up to 60 dev available on a PSO	11.07	177	- monitorito
b) Maximum of 60 dev per prescription			
56 mm	0.07	10	✓ Moments
JU IIIIII		144	✓ Moments ✓ Moments
a) Maximum of 60 day nor proportion	11.04	144	• WOUNGINS
a) Maximum of 60 dev per prescription			
b) Up to 60 dev available on a PSO	4.00	10	✓ Oald Kalalit
56 mm, 0.05 mm thickness		12	✓ Gold Knight
\	15.57	144	✓ Gold Knight
a) Up to 60 dev available on a PSO			
b) Maximum of 60 dev per prescription		4	40.11.
56 mm, 0.05mm thickness (bulk pack)	14.61	144	✓ Gold Knight
 a) Maximum of 60 dev per prescription 			
b) Up to 60 dev available on a PSO			_
56 mm, 0.08 mm thickness		10	✓ Moments
	11.64	144	✓ Moments
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	✓ Moments
	11.64	144	✓ Moments
a) Up to 60 dev available on a PSO			
b) Maximum of 60 dev per prescription			
56 mm, chocolate	1.30	12	✓ Gold Knight
,	15.57	144	✓ Gold Knight
a) Up to 60 dev available on a PSO			
b) Maximum of 60 dev per prescription			
56 mm, strawberry	1.30	12	✓ Gold Knight
00 mm, 000mp	15.57	144	✓ Gold Knight
a) Up to 60 dev available on a PSO	10.07	, 77	- Gold Killgill
b) Maximum of 60 dev per prescription	1.40	10	. Cald Value VI
60 mm		12	✓ Gold Knight XL
	14.87	144	Shield XL
a) .Maximum.of.60.dev per prescription	17.02		✓ Gold Knight XL

a) **Maximumosidised**ev per prescription b) **Hindosississis**vailable on a PSO

GENITO-URINARY SYSTEI

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
*	60 mm (bulk pack)	14.87	144	•	Gold Knight XL
C	ontracentive Devices				

ontraceptive Devices

INTRA-UTERINE DEVICE

- a) Up to 40 dev available on a PSO

	b) Only on a PSO			
*	IUD 29.1 mm length × 23.2 mm width	18.45	1	✓ Choice TT380 Short
*	IUD 33.6 mm length × 29.9 mm width	18.45	1	✓ Choice
	-			TT380 Standard
*	IUD 35.5 mm length × 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 Fither:
 - 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 - U	p to		
	84 tab available on a PSO	10.00	84	Mercilon 28

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	I Generic
	\$	Per	•	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	84	✓	Microgynon 20 ED
	6.45	112	1	Femme-Tab ED
* Tab 30 mcg with levonorgestrel 150 mcg	6.62	63		
	(16.50)			Microgynon 30
 a) Higher subsidy of \$15.00 per 63 tab with Special Auti b) Up to 63 tab available on a PSO 	hority see SA0500 or	the p	previous p	age
* Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets	_			
Up to 112 tab available on a PSO	1.77	84	✓	Levlen ED
•	6.45	112	✓	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	1	Brevinor 1/28
Tab 35 mcg with norethisterone 500 mcg and 7 inert tab - U	lp			
to 84 tab available on a PSO	•	84	•	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: Fither:

- 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 imp	plant (2 × 75 mg rods) - Up to 3 pack available			
on a PSO		106.92	1	✓ <u>Jadelle</u>
MEDROXYPROGE	ESTERONE ACETATE			
Inj 150 mg per	ml, 1 ml syringe - Up to 5 inj available on a PSO	7.98	1	✓ <u>Depo-Provera</u>
NORETHISTERON	NE			
Tab 350 mcg	- Up to 84 tab available on a PSO	12.25	84	✓ Noriday 28

Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic	
(Manuacturer's Frice)		oubsidised	Generic	
\$	Per	/	Manufacturer	

Emergency Contraceptives

LEVONORGESTREL

- - 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

Gynaecological Anti-infectives

Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate	
0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator 8.43	100 g OP
(04.00)	

(24.00) Aci-Jel

CLOTRIMAZOLE

* Vaginal crm 1% with applicators......2.50 35 g OP

NYSTATIN

Vaginal crm 100,000 u per 5 g with applicator(s)4.00 75 g OP ✓ <u>Nilstat</u>

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

OESTRIOL

	Crm 1 mg per g with applicatorPessaries 500 mcg	15 g OP 15	✓ <u>Ovestin</u> ✓ <u>Ovestin</u>
ΟX	(YTOCIN – Up to 5 inj available on a PSO		

OXYTOCIN WITH ERGOMETRINE MALEATE - Up to 5 inj available on a PSO	
Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml30.00	

✓ Oxytocin BNM✓ Oxytocin BNM

✓ Syntometrine

✓ Clomazol

✓ Clomazol

GENITO-URINARY SYSTEM

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

Pregnancy Tests - hCG Urine

PREGNANCY TESTS - HCG URINE

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

> Smith BioMed Rapid Pregnancy Test

Urinary Agents

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 107

5-Alpha Reductase Inhibitors

FINASTERIDE – Special Authority see SA0928 below – Retail pharmacy

* Tab 5 mg4.81 100

Ricit

⇒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:

- 1 Patient has symptomatic benign prostatic hyperplasia; and
- 2 Either:
 - 2.1 The patient is intolerant of non-selective alpha blockers or these are contraindicated; or
 - 2.2 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

⇒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:

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

Other Urinary Agents

OXYBUTYNIN - Subsidy by endorsement

Subsidy by endorsement – Subsidised for patients who were taking oxybutynin prior to 1 June 2021 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of oxybutynin.

*	Tab 5 mg5.42	100	✓ Alchemy
			Oxybutynin S29
	11.70	500	✓ Apo-Oxybutynin
*	Oral liq 5 mg per 5 ml60.40	473 ml	✓ Apo-Oxybutynin

(Apo-Oxybutynin Tab 5 mg to be delisted 1 May 2022) (Apo-Oxybutynin Oral lig 5 mg per 5 ml to be delisted 1 May 2022)

S29 Unapproved medicine supplied under Section 29
Sole Subsidised Supply

	Subsidy		Fully	Brand or
	(Manufacturer's Pr	ice) Su Per	osidised ✓	Generic Manufacturer
POTASSIUM CITRATE				
Oral liq 3 mmol per ml — Special Authority see SA1083 be Retail pharmacy		200 ml OP	✓ B	liomed
⇒SA1083 Special Authority for Subsidy				
nitial application from any relevant practitioner. Approvals visoth: 1 The patient has recurrent calcium oxalate urolithiasis; a 2 The patient has had more than two renal calculi in the two renal calculi from any relevant practitioner. Approvals valid for 2	nd wo years prior to the	e application		· ·
nitial application from any relevant practitioner. Approvals vi 3oth: 1 The patient has recurrent calcium oxalate urolithiasis; a 2 The patient has had more than two renal calculi in the to	nd wo years prior to the years where the trea	e application	ins appro	· ·

ORTHO-TOLIDINE			
* Compound diagnostic sticks	7.50	50 test OP	
· •	(8.25)		Hemastix
TETRABROMOPHENOL			
* Blue diagnostic strips	7.02	100 test OP	
· ,	(13.92)		Albustix

Obstetric Preparations

Antiprogesterones

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

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

Subsidy	Fı	ılly	Brand or
(Manufacturer's Price)	Subsidis	ed	Generic
\$	Per	/	Manufacturer

Calcium Homeostasis

CALCITONIN			
* Inj 100 iu per ml, 1 ml ampoule	121.00	5	✓ Miacalcic
CINACALCET - Special Authority see SA1618 below - Retail pha	armacy		
Tab 30 mg - Wastage claimable	42.06	28	✓ Cinacalet Devatis
	210.30		✓ Sensipar
Cinacalet Devatis to be Principal Supply on 1 April 2022			
Tab 60 mg - Wastage claimable	84.12	28	Cinacalet Devatis
Cinacalet Devatis to be Principal Supply on 1 April 2022			
(Canainar Tab 20 mg to be delicted 1 April 2000)			

(Sensipar Tab 30 mg to be delisted 1 April 2022)

⇒SA1618 Special Authority for Subsidy

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

Fither:

- 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 arteriolopathy); 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 < 3mmol/L; and
- 2 The patient has experienced clinically significant symptom improvement.

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

70I FDRONIC ACID

⇒SA2031 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

	Subsidy		Fully	Brand or
(Mai	nufacturer's Price)	Subsi	dised	Generic
	\$	Per	✓	Manufacturer

continued...

surgery to bone.

Initial application — (early breast cancer) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

1 Treatment to be used as adjuvant therapy for early breast cancer; and

BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETATE

- 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 2 years.

Corticosteroids and Related Agents for Systemic Use

ВE	TAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE	ACETATE		
*	Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	.19.20	5	
		(36.96)		Celestone
				Chronodose
DE	XAMETHASONE			
*	Tab 0.5 mg - Up to 60 tab available on a PSO	1 50	30	✓ Dexmethsone
	Tab 4 mg - Up to 30 tab available on a PSO		30	✓ Dexmethsone
~	Oral lig 1 mg per ml		25 ml OP	✓ Biomed
		.40.13	23 IIII OF	• bioilieu
DE	XAMETHASONE 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	9.25	10	✓ <u>Dexamethasone</u> <u>Phosphate</u> Panpharma
*	Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	.16.37	10	✓ Dexamethasone Phosphate Panpharma
FL	JDROCORTISONE ACETATE			
*	Tab 100 mcg	.14.32	100	✓ Florinef
	DROCORTISONE			
*	Tab 5 mg	8 10	100	✓ Douglas
	Tab 20 mg		100	✓ Douglas ✓ Douglas
	· ·		1	✓ Solu-Cortef
*	Inj 100 mg vial	4.30	ı	Solu-Corter
	a) Up to 5 inj available on a PSO			
	b) Only on a PSO			
ME	THYLPREDNISOLONE			
*	Tab 4 mg	112.00	100	✓ Medrol
*	Tab 100 mg	223.10	20	✓ Medrol
ME	THYLPREDNISOLONE (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

	Subsidy	,	Fully	Brand or
	(Manufacturer's Pric	e) Sub: Per	sidised •	Generic Manufacturer
ETHYLPREDNISOLONE ACETATE	· ·			
Inj 40 mg per ml, 1 ml vial	47.06	5	✓	Depo-Medrol
REDNISOLONE		·		- opoou.o.
Oral liq 5 mg per ml – Up to 30 ml available on a PSO Restricted to children under 12 years of age.	6.00	30 ml OP	✓	<u>Redipred</u>
REDNISONE				
: Tab 1 mg	18.58	500		Apo-Prednisone
	24.24	500	_	Prednisone Clinect
F Tab 2.5 mg	21.04	500		Apo-Prednisone Prednisone Clinect
Tab 5 mg - Up to 30 tab available on a PSO	10.30	500		Apo-Prednisone
Tab 3 mg - op to 30 tab available on a 1 30	19.00	300		Prednisone Clinect
F Tab 20 mg - Up to 30 tab available on a PSO	50.51	500	1	Apo-Prednisone Prednisone Clinect
Apo-Prednisone Tab 1 mg to be delisted 1 November 2022) Apo-Prednisone Tab 2.5 mg to be delisted 1 November 2022) Apo-Prednisone Tab 5 mg to be delisted 1 November 2022) Apo-Prednisone Tab 20 mg to be delisted 1 November 2022)				
ETRACOSACTRIN				
Inj 250 mcg per ml, 1 ml ampoule	75.00	1		UK Synacthen S29
				AU Synacthen
for Inj 1 mg per ml, 1 ml ampoule	690.00	1	1	Synacthen Synacthen Depot Synacthene Retard S29
RIAMCINOLONE ACETONIDE				
Inj 10 mg per ml, 1 ml ampoule	20.80	5	✓	Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule		5		Kenacort-A 40
Sex Hormones Non Contraceptive				
Androgen Agonists and Antagonists				
YPROTERONE ACETATE				
Tab 50 mg	14.37	50	1	Siterone
Tab 100 mg	28.03	50	1	Siterone
ESTOSTERONE				
Patch 5 mg per day	90.00	30	1	Androderm
ESTOSTERONE CIPIONATE				
Inj 100 mg per ml, 10 ml vial	85.00	1	✓	Depo-Testosterone
ESTOSTERONE ESTERS				
Inj 250 mg per ml, 1 ml	12.98	1	1	Sustanon Ampoules
ESTOSTERONE UNDECANOATE				•
Cap 40 mg - Subsidy by endorsement	21.00	60	1	Andriol Testocaps
Subsidy by endorsement - subsidised for patients who was	were taking testoste	erone undec	anoate	cap 40mg prior to
1 November 2021 and the prescription is endorsed acco	ordingly. Pharmacis	sts may ann	otate th	ne prescription as endo
where there exists a record of prior dispensing of testost	terone undecanoate		in the	preceding 12 months.
Inj 250 mg per ml, 4 ml vial	86.00	1	✓	Reandron 1000

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

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		28 OP	
* Tab 2 mg	(11.10)	28 OP	Estrofem
本 Tab 2 Hig	(11.10)	20 UF	Estrofem
Patch 25 mcg per day		8	✓ Estradot
	7.85		Estradiol TDP
			Mylan S29
No more than 2 patch per week			
b) Only on a prescription Patch 50 mcg per day	7.04	8	✓ Estradot 50 mcg
Falcit 50 mcg per day	9.22	O	✓ Estradiol TDP
			Mylan S29
a) No more than 2 patch per week			•
b) Only on a prescription			
Patch 75 mcg per day		8	✓ Estradot
	10.60		✓ Estradiol TDP Mylan S29
a) No more than 2 patch per week			IVI y Idi 1 329
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			
(Estradiol TDP Mylan S29 Patch 25 mcg per day to be delisted 1	,		
(Estradiol TDP Mylan 829 Patch 50 mcg per day to be delisted 1	, ,		
(Estradiol TDP Mylan S29 Patch 75 mcg per day to be delisted 1	May 2022)		
OESTRADIOL VALERATE – See prescribing guideline above * Tab 1 mg	12 36	84	✓ Progynova
* Tab 2 mg		84	✓ Progynova
OESTROGENS - See prescribing guideline above			3,7
* Conjugated, equine tab 300 mcg	3.01	28	
	(17.50)		Premarin
* Conjugated, equine tab 625 mcg		28	Duamanin
	(17.50)		Premarin
Progestogens			
MEDROXYPROGESTERONE ACETATE - See prescribing guide	eline above		
* Tab 2.5 mg		30	✓ Provera
* Tab 5 mg		100	✓ Provera
* Tab 10 mg	8.94	30	✓ Provera

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

Subsidy

Fully

Brand or

	(Manufacturer's Price) \$	Per	sidised •	Generic Manufacturer	
Progestogen and Oestrogen Combined Prepara	ations				
OESTRADIOL WITH NORETHISTERONE – See prescribing gu * Tab 1 mg with 0.5 mg norethisterone acetate		us page 28 OP			

OESTRADIOL WITH NORETHISTER	RONE – See prescribing gui	deline on the pre	vious page	
* Tab 1 mg with 0.5 mg norethister	one acetate	5.40	28 OP	
		(18.10)		Kliovance
* Tab 2 mg with 1 mg norethisteror	ne acetate	5.40	28 OP	
		(18.10)		Kliogest
* Tab 2 mg with 1 mg norethisteror	ne acetate (10), and 2 mg			
oestradiol tab (12) and 1 mg	oestradiol tab (6)	5.40	28 OP	
		(18.10)		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
(NZ Medical and Scientific Tab 10 mcg to be delisted 1 Febr	uary 2023)		Scientific

OESTRIOL

Other Progestogen Preparations

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vera HD
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1

⇒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 Fither:
 - 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

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

continued...

- 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

CA	RBIMAZOLE			
*	Tab 5 mg	10.80	100	✓ Neo-Mercazole
LE	VOTHYROXINE			
*	Tab 25 mcg	5.55	90	✓ Synthroid
	Tab 50 mcg		28	✓ Mercury Pharma
	•	5.79	90	✓ Synthroid
		64.28	1,000	✓ Eltroxin
*	Tab 100 mcg	1.78	28	✓ Mercury Pharma
	•	6.01	90	✓ Synthroid
		66.78	1,000	✓ Eltroxin

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.

⇒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

SO	MATROPIN (OMNITROPE) - Special Authority see SA2032 belo	w – Retail p	charmacy	
*	Inj 5 mg cartridge	69.75	ĺ	✓ Omnitrope
*	Inj 10 mg cartridge	69.75	1	✓ Omnitrope
*	Inj 15 mg cartridge	139.50	1	✓ Omnitrope

⇒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:

Fither:

- 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</p>
- 2 All of the following:

Subsidy (Manufacturer's Price)	F Subsidi	ully	Brand or Generic
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- 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:

- 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:

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

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

Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic
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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

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

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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- 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, syringe65.68	1	✓ Teva
Implant 10.8 mg, syringe122.37	1	✓ Teva
LEUPRORELIN		
Additional subsidy by endorsement where the patient is a child or adolescent and goserelin and the prescription is endorsed accordingly.	d is unable	to tolerate administration of
Inj 3.75 mg prefilled dual chamber syringe - Higher subsidy of		
\$221.60 per 1 inj with Endorsement	1	
(221.60)		Lucrin Depot 1-month
Inj 11.25 mg prefilled dual chamber syringe - Higher subsidy		
of \$591.68 per 1 inj with Endorsement177.50	1	
(591.68)		Lucrin Depot 3-month

Vasopressin Agonists

DESMOPRESSIN			
Wafer 120 mcg	47.00	30	Minirin Melt

	Subsidy (Manufacturer's Price \$	e) Sub Per	Fully sidised	Brand or Generic Manufacturer
DESMOPRESSIN ACETATE				
Tab 100 mcg	25.00	30	✓ N	linirin
Tab 200 mcg	54.45	30	✓ N	linirin
▲ Nasal spray 10 mcg per dose		6 ml OP	✓ <u>D</u>	esmopressin-
				PH&T
Inj 4 mcg per ml, 1 ml	67.18	10	✓ N	linirin

Other Endocrine Agents

CABERGOLINE

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

⇒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	
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Tab 50 mg	29.84	10	✓ Mylan Clomiphen S29
METYRAPONE Cap 250 mg	558.00	50	✓ Metopirone

INFECTIONS - AGENTS FOR SYSTEMIC USE Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer **Anthelmintics** ALBENDAZOLE - Special Authority see SA1318 below - Retail pharmacy 60 Fskazole S29 ⇒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 mg7.97 6 Vermox 15 ml (7.53)Vermox PRAZIQUANTFI 8 Biltricide **Antibacterials** a) For topical antibacterials, refer to DERMATOLOGICALS, page 61 b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 235 Cephalosporins and Cephamycins CEFACLOR MONOHYDRATE Cap 250 mg......24.70 ✓ Ranbaxy-Cefaclor 100 ✓ Ranbaxy-Cefaclor S29 S29 ✓ Ranbaxy-Cefaclor 100 ml ✓ Ranbaxy-Cefaclor S29 S29 **CEFALEXIN** 20 ✓ Cephalexin ABM ✓ Cephalexin ABM 20 Grans for oral lig 25 mg per ml - Wastage claimable......8.75 100 ml ✓ Cefalexin Sandoz ✓ Cefalexin Sandoz Grans for oral lig 50 mg per ml - Wastage claimable......11.75 100 ml CEFAZOLIN - Subsidy by endorsement Only if prescribed for dialysis or cellulitis in accordance with a DHB approved protocol and the prescription is endorsed accordingly. CEFTRIAXONE - Subsidy by endorsement a) Up to 10 ini 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.

CEFUROXIME AXETIL — Subsidy by endorsement

Only if prescribed for prophylaxis of endocarditis and the prescription is endorsed accordingly

✓ Ceftriaxone-AFT✓ Ceftriaxone-AFT

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

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

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

Tab 250 mg	8.19	30	✓ Apo-Azithromycin
Tab 500 mg - Up to 8 tab available on a PSO		2	✓ Zithromax
Grans for oral liq 200 mg per 5 ml (40 mg per ml) - Wastage			
claimable	16.97	15 ml	✓ Zithromax

(Apo-Azithromycin Tab 250 mg to be delisted 1 May 2022)

⇒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 Fither:
 - 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

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 clai	mable	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:

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Sub	osidised	Generic	
\$	Per	1	Manufacturer	

continued...

1 Atypical mycobacterial infection; or

EDVELIDOMAYCINI (AC LACTORIONIATE)

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
ERYTHROMYCIN ETHYL SUCCINATE			<u>,</u>
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	5.00	400 1	4 = 11 ·
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 RFPPc) 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			
ERYTHROMYCIN STEARATE			
Tab 250 mg - Up to 30 tab available on a PSO	14.95	100	
	(22.29)		ERA
Tab 500 mg		100	EDA.
(FDA Tab 050 mg to be delicted 1 April 2000)	(44.58)		EHA
, ,			
, ,			
	8 29	10	✓ Rulide D
	0.20	10	· Hullac D
Tab 150 mg	8.28	50	✓ Arrow-
•			Roxithromycin
Tah 300 mg	16 33	50	✓ Arrow-
1 ab 000 filg	10.00	50	Roxithromycin
Tab 500 mg	8.29 8.28	100 10 50 50	Roxithromycin Arrow-

	Subsidy (Manufacturer's Price))	Fully Subsidised	
	\$	Per	1	Manufacturer
Penicillins				
AMOXICILLIN				
Cap 250 mg	22.50	500	•	<u>Alphamox</u>
Cap 500 mg	36.98	500	1	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 m	ı v	Alphamox 125
a) Up to 200 ml available on a PSOb) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	1.73	100 m	· •	Alphamox 250
Inj 250 mg vial	15.97	10	1	Ibiamox
Inj 500 mg vial		10	1	Ibiamox
Inj 1 g vial - Up to 5 inj available on a PSO	21.64	10	1	Ibiamox
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg - Up to 30 tab				
available on a PSO	0.89	10	1	Curam Duo 500/125
Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25				
per ml		100 m	· •	Augmentin
a) Up to 200 ml available on a PSOb) Wastage claimable				·
Grans for oral liq amoxicillin 50 mg with clavulanic acid 12.5 per ml – Up to 200 ml available on a PSO		00 ml (OP 🗸	Curam
BENZATHINE BENZYLPENICILLIN				
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
BENZYLPENICILLIN SODIUM [PENICILLIN G] Inj 600 mg (1 million units) vial – Up to 5 inj available on a P	SO 11.09	10	•	Sandoz

	Subsidy		Fully	
	(Manufacturer's Price \$) Per	Subsidised	d Generic Manufacturer
LUCLOXACILLIN	Ψ	1 01		Manadator
Cap 250 mg - Up to 30 cap available on a PSO	15 70	250	1	Flucloxacillin-AFT
Cap 250 mg - Op to 50 cap available on a F50	15.79	200		Staphlex
Flucloxacillin-AFT to be Principal Supply on 1 May 2022				Otupinox
Cap 500 mg - Up to 30 cap available on a PSO		500	1	Flucloxacillin-AFT
			1	Staphlex
Flucloxacillin-AFT to be Principal Supply on 1 May 2022				•
Grans for oral liq 25 mg per ml	3.29	100 m	 	<u>AFT</u>
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 50 mg per ml	3.68	100 m	· •	<u>AFT</u>
a) Up to 200 ml available on a PSO				
b) Wastage claimable	47.50	40	,	Floretonic
Inj 250 mg vial		10		Flucioxin Flucioxin
Inj 500 mg vialInj 1 g vial – Up to 5 inj available on a PSO		10 5		Flucio
Staphlex Cap 250 mg to be delisted 1 May 2022)	5.70	5	•	<u>FIUCII</u>
Staphlex Cap 500 mg to be delisted 1 May 2022)				
HENOXYMETHYLPENICILLIN (PENICILLIN V)	2 04	50	_	Cilicaine VK
Cap 250 mg - Up to 30 cap available on a PSO Cap 500 mg		50 50		Cilicaine VK
a) Up to 20 cap available on a PSO		50	•	Omeanic VIX
b) Up to 2 x the maximum PSO quantity for RFPP				
Grans for oral liq 125 mg per 5 ml	2.99	100 m	· •	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	3.99	100 m	 	<u>AFT</u>
a) Up to 300 ml available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP				
c) Wastage claimable				
ROCAINE PENICILLIN				
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO	123.50	5	•	Cilicaine
Tetracyclines				
OXYCYCLINE				
♥ Tab 100 mg – Up to 30 tab available on a PSO	64 43	500	1	Doxine
INOCYCLINE HYDROCHLORIDE		550	•	
Tab 50 mg - Additional subsidy by Special Authority see				
SA1355 below – Retail pharmacy	5 79	60		
Control bolon Floral pharmacy	(12.05)	50		Mino-tabs
€ Cap 100 mg		100		
	(52.04)			Minomycin
SA1355 Special Authority for Manufacturers Price				
nitial application from any relevant practitioner. Approvals vali	d without further ren	ewal ur	nless noti	fied where the patient has
osacea.				
ETRACYCLINE - Special Authority see SA1332 on the next page 1	age – Retail pharma	су		
Tab 250 mg	21.42	28	•	Accord S29

Subsidy	Fully	Brand or
(Manufacturer's		Generic
\$	Per 🗸	Manufacturer

⇒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		28	✓ Cipflox
Tab 750 mg		28	✓ Cipflox
· ·		20	<u> Olphox</u>
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 – S			ordinaly
Only if prescribed for dialysis or cystic fibrosis patient and the		uorseu acc	0,
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 of endorsed accordingly.			
Inj 10 mg per ml, 2 ml ampoule - Subsidy by endorsement	91.00	5	✓ Wockhardt S29
, , , ,	182.00	10	✓ Teligent S29
Only if prescribed for a dialysis or cystic fibrosis patient			•
endorsed accordingly.	or complicated unit	ary tractim	ection and the prescription is
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 of endorsed accordingly.	or complicated urin	ary tract inf	fection and the prescription is
MOXIFLOXACIN - Special Authority see SA1740 below - Retail	I nharmacy		
No patient co-payment payable	priarriady		
	40.00	_	A Aveley
Tab 400 mg	42.00	5	✓ <u>Avelox</u>

⇒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

Subsidy (Manufacturer's Price)	,		Brand or Generic
 \$	Per	•	Manufacturer

continued...

- 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: ٥r
- 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
- - 2.1 Has tried and failed to clear infection using azithromycin; or
 - 2.2 Has laboratory confirmed azithromycin resistance; and
 - 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

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 histolyica carriage.

Renewal only from an infectious disease specialist, clinical microbiologist or gastroenterologist. Approvals valid for 1 month for applications meeting the following criteria:

Fither:

- 1 Patient has confirmed cryptosporidium infection; or
- 2 For the eradication of Entamoeba histolyica carriage.

PYRIMETHAMINE - Special Authority see SA1328 below - Retail pharmacy

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 mg67.85 36 ✓ Fucidin

	Subsidy (Manufacturer's Price) \$) Sub	Fully Brand or sidised Generic Manufacturer
SULFADIAZINE SODIUM – Special Authority see SA1331 below Tab 500 mg		56	✓ Wockhardt ©29
■ SA1331 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria: Any of the following: 1 For the treatment of toxoplasmosis in patients with HIV for 2 For pregnant patients for the term of the pregnancy; or 3 For infants with congenital toxoplasmosis until 12 months of the pregnancy.	a period of 3 month		ss notified for applications meeting
TOBRAMYCIN	or age.		
Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement Only if prescribed for dialysis or cystic fibrosis patient and		5 endorsed	✓ <u>Tobramycin Mylan</u> accordingly.
Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsement		56 dose	✓ Tobramycin BNM
a) Wastage claimable b) Only if prescribed for a cystic fibrosis patient and the			
TRIMETHOPRIM			
* Tab 300 mg - Up to 30 tab available on a PSO		50	✓ <u>TMP</u>
TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOX/ * Tab trimethoprim 80 mg and sulphamethoxazole 400 mg - L	Jp .		
to 30 tab available on a PSO* * Oral liq 8 mg sulphamethoxazole 40 mg per ml - Up to 200 r		500	✓ <u>Trisul</u>
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 difficile following metronidazole failure and the prescription is	endorsed according	gly.	
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	2		
FLUCONAZOLE			
Cap 50 mg	2.75	28	✓ Mylan
Cap 150 mg		1	✓ <u>Mylan</u>
Cap 200 mg		28	✓ <u>Mylan</u>
Powder for oral suspension 10 mg per ml — Special Authority see SA1359 below — Retail pharmacy		35 ml	✓ Diflucan
⇒SA1359 Special Authority for Subsidy			for Overales for any live time

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

Subsidy		Fully	Brand or
(Manufacturer's Price)	Subs	sidised	Generic
\$	Per	•	Manufacturer

continued...

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 mg4	1.27	15	✓ <u>Itrazole</u>
Oral liq 10 mg per ml - Special Authority see SA1322 below -			
Retail pharmacy141	.80	150 ml OP	✓ Sporanox

⇒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 ✓ Nizoral S29
		100	✓ Strides Shasun S29
NYSTATIN			
Tab 500,000 u	.14.16	50	
	(17.09)		Nilstat
Cap 500,000 u	.12.81	50	
	(15.47)		Nilstat
POSACONAZOLE - Special Authority see SA1285 below - Retail pha	rmacy		
Tab modified-release 100 mg	369.86	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

Subsid (Manufacturer		Fully sidised	Brand or Generic	
(Manuacture)	Per Per	siuiseu	Manufacturer	

continued...

therapy*.

Renewal only from a haematologist or infectious disease specialist. Approvals valid for 6 weeks for applications meeting the following criteria:

Fither:

- 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

TETION VIII IVE			
* Tab 250 mg	8.15	84	✓ Deolate
VORICONAZOLE - Special Authority see SA1273 below - Ret	ail 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

⇒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



Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
<u> </u>	Per 🗸	Manufacturer

⇒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		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	✓ <u>Arrow-Ornidazole</u>
Antituberculotics and Antileprotics			
Note: There is no co-payment charge for all pharmaceuticals lis	stad in the Antitube	arculation and	Antilopratics group regardless of
immigration status.	sted in the Antitude	erculotics and	Antilieprolics group regardless of
CLOFAZIMINE - Retail pharmacy-Specialist			
a) No patient co-payment payable			
b) Prescriptions must be written by, or on the recommenda	tion of, an infectio	us disease ph	nysician, clinical microbiologist or
dermatologist.			
* Cap 50 mg	442.00	100	✓ Lamprene S29
CYCLOSERINE - Retail pharmacy-Specialist			
a) No patient co-payment payable			
b) Prescriptions must be written by, or on the recommenda	tion of, an infectio	us disease ph	nysician, clinical microbiologist or
respiratory physician.	044.00	20	40.1.1
Cap 250 mg	344.00	60	✓ Cyclorin S29
DAPSONE - Retail pharmacy-Specialist			
 a) No patient co-payment payable 			
 b) Prescriptions must be written by, or on the recommenda dermatologist 	tion of, an infectio	us disease ph	nysician, clinical microbiologist or
Tab 25 mg	268.50	100	✓ Dapsone
Tab 100 mg	329.50	100	Dapsone
ETHAMBUTOL HYDROCHLORIDE - Retail pharmacy-Special	ist		
a) No patient co-payment payable			
 Prescriptions must be written by, or on the recommendarespiratory physician 	tion of, an infectio	us disease ph	nysician, clinical microbiologist or
Tab 100 mg	85.73	100	✓ EMB Fatol S29
T 400			

56

Tab 400 mg49.34

Myambutol \$29

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
SONIA	AZID - Retail pharmacy-Specialist				
b)	No patient co-payment payable Prescriptions must be written by, or on the recommendati microbiologist, dermatologist or public health physician				
	b 100 mg	23.00	100	/	PSM
	AZID WITH RIFAMPICIN - Retail pharmacy-Specialist				
	No patient co-payment payable Prescriptions must be written by, or on the recommendati microbiologist, dermatologist or public health physician	on of, an internal me	dicine	physician	, paediatrician, clinical
€ Ta	b 100 mg with rifampicin 150 mg	89.82	100	1	Rifinah
· Ta	b 150 mg with rifampicin 300 mg	179.13	100	1	<u>Rifinah</u>
ARA-	AMINO SALICYLIC ACID - Retail pharmacy-Specialist				
b)	No patient co-payment payable Prescriptions must be written by, or on the recommendati respiratory physician		liseas	e specialis	t, clinical microbiologist o
Gr	ans for oral liq 4 g sachet	280.00	30	✓	Paser S29
ROTI	ONAMIDE - Retail pharmacy-Specialist				
b)	No patient co-payment payable Prescriptions must be written by, or on the recommendati respiratory physician				
	b 250 mg	305.00	100	•	Peteha S29
	ZINAMIDE – Retail pharmacy-Specialist				
b)	No patient co-payment payable Prescriptions must be written by, or on the recommendati respiratory physician		liseas	e physicia	n, clinical microbiologist o
€ Ta	b 500 mg	64.95	100	•	AFT-Pyrazinamide
IFABI	UTIN - Retail pharmacy-Specialist				
b)	No patient co-payment payable Prescriptions must be written by, or on the recommendati gastroenterologist				
	p 150 mg	299.75	30	•	Mycobutin
	PICIN – Subsidy by endorsement				
b)	No patient co-payment payable For confirmed recurrent Staphylococcus aureus infection antimicrobial based on susceptibilities and the prescription Retail pharmacy - Specialist. Specialist must be an interr paediatrician, or public health physician.	n is endorsed accord nal medicine physicia	lingly; ın, clir	can be wa nical micro	aived by endorsement - biologist, dermatologist,
	ıp 150 mgp 300 mg		100 100	_	Rifadin Rifadin
	al liq 100 mg per 5 ml		60 m		Rifadin
Oil	arily 100 mg per 3 mi	12.00	00 111	•	maum
Anti	virals				
or eye	e preparations refer to Eye Preparations, Anti-Infective Pre	parations, page 235			
Нера	atitis B Treatment				
	CAVIR				
NTEC	27 (🕶 11 (

	Subsidy (Manufacturer's P	rice)	Fully Subsidised	Brand or Generic	
	\$	Per	1	Manufacturer	
LAMIVUDINE - Special Authority see SA1685 below - Retail ph	armacy				
Tab 100 mg	6.95	28	✓ <u>Z</u>	<u>'etlam</u>	
Oral liq 5 mg per ml	270.00	240 ml C)P √ Z	Zeffix	
0.4005					

⇒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 DISOPROXII

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 SA1651., page 104

★ Tab 245 mg (300.6 mg as a succinate).......38.10
30 ✓ Tenofovir Disoproxil
Teva

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
VALACICLOVIR			
Tab 500 mg	6.50	30	✓ Vaclovir
Tab 1,000 mg	13.76	30	✓ Vaclovir
VALGANCICLOVIR - Special Authority see SA199	3 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:

Fither:

- 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.

Subsidy		Fully	Brand or	
(Manufacturer's Price)	9	Subsidised	Generic	
\$	Per	✓	Manufacturer	

continued...

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:

- 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 mg24,750.00 84 OP ✓ Maviret

LEDIPASVIR WITH SOFOSBUVIR - [Xpharm] - Special Authority see SA1605 below

No patient co-payment payable

⇒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

Subsidy (Manufacturer's Price) \$ Per

Fully Subsidised Brand or Generic Manufacturer

HIV Prophylaxis and Treatment

EMTRICITABINE WITH TENOFOVIR DISOPROXIL — Subsidy by endorsement; can be waived by Special Authority see SA1994 below

below
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 SA1651 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 SA1651, page 104 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.

30 ✓ Teva

⇒SA1994 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria: All of the following:

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

Renewal from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria: All of the following:

- 1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and
- 2 Patient has undergone testing for HIV, syphilis and Hep B if not immune and a full STI screen in the previous two weeks; and
- 3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 12 months and is not contraindicated for treatment; and
- 4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce

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

continued...

those risks: and

- 5 Patient has tested HIV negative and is not at risk of HIV seroconversion; and
- 6 Fither:
 - 6.1 All of the following:
 - 6.1.1 Patient is male or transgender; and
 - 6.1.2 Patient has sex with men; and
 - 6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and
 - 6.1.4 Any of the following:
 - 6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
 - 6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or
 - 6.1.4.3 Patient has used methamphetamine in the last three months; or
 - 6.2 All of the following:
 - 6.2.1 Patient has a regular partner who has HIV infection; and
 - 6.2.2 Partner is either not on treatment or has a detectable viral load; and
 - 6.2.3 Condoms have not been consistently used.

Antiretrovirals

⇒SA1651 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:

- 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 non-occupational exposure to HIV) only from a named specialist. 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 unprotected receptive anal intercourse with a known HIV positive person; or

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

continued...

- 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.

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 post-exposure prophylaxis) only from a named specialist. 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 unprotected receptive anal intercourse with a known HIV positive person; 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.

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.

Non-nucleosides Reverse Transcriptase Inhibitors

EFAVIRENZ - Special Authority see SA1651 on t	he previous page - Retail pharm	nacy	
Tab 200 mg	190.15	90	✓ Stocrin
Tab 600 mg	63.38	30	✓ Stocrin
ETRAVIRINE - Special Authority see SA1651 on	the previous page - Retail phan	macy	
Tab 200 mg	770.00	60	✓ Intelence
NEVIRAPINE - Special Authority see SA1651 on	the previous page - Retail phare	macy	
Tab 200 mg	84.00	60	✓ <u>Nevirapine</u>
			<u>Alphapharm</u>
Oral suspension 10 mg per ml	203.55	240 ml	✓ Viramune
			Suspension

Nucleosides Reverse Transcriptase Inhibitors

ABACAVIR SULPHATE - Special Authority see SAT651 on the	ne previous page – r	retali pharmac	cy .
Tab 300 mg	180.00	60	✓ Ziagen
Oral liq 20 mg per ml	256.31	240 ml OP	✓ Ziagen
ABACAVIR SULPHATE WITH LAMIVUDINE - Special Autho			
Note: abacavir with lamivudine (combination tablets) could	nts as two anti-retrov	riral medication	ns for the purposes of the
anti-retroviral Special Authority.			
Tab 600 mg with lamivudine 300 mg	63.00	30	✓ Kivexa

	Subsidy		Fully	Brand or
	(Manufacturer's Price		dised	Generic
	\$	Per	✓	Manufacturer
EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOP	ROXII - Special A	uthority see §	SA1651	1 on page 104 – Retail
pharmacy	TOTAL OPOOIGIT	idinomy ooo c	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	r on page 101 Tiolan
Note: Efavirenz with emtricitabine and tenofovir disoproxil c	ounts as three anti-	retroviral med	dication	ns for the nurnoses of the
anti-retroviral Special Authority	ounto do unoc anu	Totrovirai met	aloutioi	io for the purposes of the
• • • • • • • • • • • • • • • • • • • •	vil			
Tab 600 mg with emtricitabine 200 mg and tenofovir disopro		20	./ N	lulan.
245 mg (300 mg as a maleate)		30	<u> </u>	<u>lylan</u>
EMTRICITABINE - Special Authority see SA1651 on page 104	 Retail pharmacy 			
Cap 200 mg	307.20	30	√ <u>E</u>	<u>mtriva</u>
LAMIVUDINE - Special Authority see SA1651 on page 104 - Re	etail pharmacy			
Tab 150 mg	, ,	60	√ 1	amivudine
Tab 100 mg	04.00	00	٠ -	Alphapharm
Oval lie 10 me nov ml	100.50	240 ml OP	√ 3	
Oral liq 10 mg per ml		-	v 3	IC
ZIDOVUDINE [AZT] - Special Authority see SA1651 on page 10	04 – Retail pharmac	су		
Cap 100 mg	152.25	100	✓ R	letrovir
Oral liq 10 mg per ml	30.45	200 ml OP	✓ R	letrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE - Special Authority see	SA1651 on page	104 – Retail r	harma	acv
Note: zidovudine [AZT] with lamivudine (combination tablets				•
the anti-retroviral Special Authority.	s) counts as two an	ili ictioviiai iii	cuican	ons for the purposes of
Tab 300 mg with lamivudine 150 mg	33.00	60	√ ∧	lphapharm
rab 500 mg with lamivudine 150 mg	33.00	00	• 4	прпарпатпі
Drotogog Inhibitoro				
Protease Inhibitors				
ATAZANAVIR SULPHATE - Special Authority see SA1651 on p	nage 104 – Retail n	harmacy		
Cap 150 mg	•	60	✓ T	eva
Cap 200 mg		60	✓ T	
		00	• 1	cva
DARUNAVIR – Special Authority see SA1651 on page 104 – Re				
Tab 400 mg		60		arunavir Mylan
Tab 600 mg	196.65	60	✓ D	arunavir Mylan
LOPINAVIR WITH RITONAVIR - Special Authority see SA1651	on page 104 - Ref	tail pharmacy		
Tab 100 mg with ritonavir 25 mg - Brand switch fee payable		, ,		
(Pharmacode 2621959) - see page 240 for details		60	√ I	opinavir/Ritonavir
(1 Hamildoode 2021000) 300 page 240 for detaile		00	• •	Mylan
Tab 200 mg with ritonavir 50 mg - Brand switch fee payable	,			<u>myran</u>
		120	./ 1	opinavir/Ritonavir
(Pharmacode 2621959) - see page 240 for details	293.00	120	• <u>L</u>	
0 11 00 11 11 10 10				<u>Mylan</u>
Oral liq 80 mg with ritonavir 20 mg per ml	735.00	300 ml OP	✓ K	aletra
RITONAVIR - Special Authority see SA1651 on page 104 - Ret	ail pharmacy			
Tab 100 mg	43.31	30	✓ N	lorvir
Ÿ				
Strand Transfer Inhibitors				
DOLUTEGRAVIR - Special Authority see SA1651 on page 104	- Retail pharmacy			
Tab 50 mg	1,090.00	30	✓ T	ivicay
RALTEGRAVIR POTASSIUM - Special Authority see SA1651 of	n nage 104 – Reta	il nharmacy		-
Tab 400 mg	1 0	60	√ la	sentress
Tab 600 mg	·	60		sentress HD
rab ood my	1,000.00	00	- 18	John God HD

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

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 × 10⁹) 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 below - 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.

✓ Pegasys

⇒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:

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Sub	sidised	Generic	
\$	Per	/	Manufacturer	

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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 Fither:
 - 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-naive; and
- 3 ALT > 2 times Upper Limit of Normal; and
- 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:

INFECTIONS - AGENTS FOR SYSTEMIC USE

Subsidy (Manufacturer's Pric	e)	Fully Subsidised	Brand or Generic	
\$	Per	· •	Manufacturer	

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- 2.1 Patient has a myeloproliferative disorder*; and
- 2.2 Patient is intolerant of hydroxyurea; and
- 2.3 Treatment with an agrelide 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 Fither:
 - 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 Fither:
 - 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-allogenic 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-allogenic bone marrow transplant) from any relevant practitioner. Approvals valid for 3 months where patient is responding and ongoing treatment remains appropriate.

Note: Indications marked with * are unapproved indications.

Urinary Tract Infections

METHENAMINE (HEXAMINE) HIPPURATE		
* Tab 1 g40.01	100	✓ Hiprex
NITROFURANTOIN		
* Tab 50 mg - Up to 30 tab available on a PSO22.20	100	✓ Nifuran
* Tab 100 mg37.50	100	✓ Nifuran
* Cap modified-release 100 mg - Wastage claimable86.40	100	✓ <u>Macrobid</u>
NORFLOXACIN		
Tab 400 mg - Subsidy by endorsement245.00	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.

	Subsidy		Fully Brand or
	(Manufacturer's Price	e) Sub	osidised Generic
	\$	Per	✓ Manufacturer
Anticholinesterases			
7 Hittorio III losto i doco			
NEOSTIGMINE METILSULFATE			
Inj 2.5 mg per ml, 1 ml ampoule	22 01	10	✓ Max Health
	00.01	10	wax ricatur
PYRIDOSTIGMINE BROMIDE			
▲ Tab 60 mg	45.79	100	✓ Mestinon
Non-Steroidal Anti-Inflammatory Drugs			
Tron Storoladi Alla lililalililator y Brago			
DICLOFENAC SODIUM			
* Tab EC 25 mg	1 99	50	✓ Diclofenac Sandoz
* Tab 50 mg dispersible		20	✓ Voltaren D
0 1			
* Tab EC 50 mg		50	✓ <u>Diclofenac Sandoz</u>
* Tab long-acting 75 mg		100	✓ Voltaren SR
	22.80	500	Apo-Diclo SR
* Tab long-acting 100 mg		500	Apo-Diclo SR
* Inj 25 mg per ml, 3 ml ampoule - Up to 5 inj available on a	PSO 13.20	5	✓ Voltaren
* Suppos 12.5 mg	2.04	10	✓ Voltaren
* Suppos 25 mg		10	✓ Voltaren
* Suppos 50 mg - Up to 10 supp available on a PSO		10	✓ Voltaren
* Suppos 100 mg		10	✓ Voltaren
5		10	Voltaren
(Apo-Diclo SR Tab long-acting 75 mg to be delisted 1 May 2022			
(Apo-Diclo SR Tab long-acting 100 mg to be delisted 1 May 202	2)		
IBUPROFEN			
* Tab 200 mg	21.40	1.000	✓ Relieve
* Tab long-acting 800 mg		30	✓ Brufen SR
* Oral lig 20 mg per ml		200 ml	✓ Ethics
	2.20	200 1111	V Eulics
Ethics to be Principal Supply on 1 April 2022			
KETOPROFEN			
* Cap long-acting 200 mg	12.07	28	✓ Oruvail SR
MEFENAMIC ACID			
	4.05		
* Cap 250 mg		50	
	(9.16)		Ponstan
	0.50	20	
	(5.60)		Ponstan
NAPROXEN			
* Tab 250 mg	20.60	500	✓ Noflam 250
•			
* Tab 500 mg		250	✓ Noflam 500
* Tab long-acting 750 mg		28	✓ Naprosyn SR 750
* Tab long-acting 1 g	8.62	28	✓ Naprosyn SR 1000
SULINDAC			
* Tab 100 mg	0.57	56	✓ Mylan S29
· ·	9.37	90	♥ Wylan 323
(Mylan S29) Tab 100 mg to be delisted 1 May 2022)			
TENOXICAM			
* Tab 20 mg	9 15	100	✓ Tilcotil
* Inj 20 mg vial		1	✓ AFT
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	IVIC	1500	JLUSKE	ELETAL SYSTEM
	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
NSAIDs Other				
CELECOXIB				
Cap 100 mg	5.80	60		Celecoxib Pfizer
Cap 200 mg		30		Celebrex
	3.30		•	Celecoxib Pfizer
Topical Products for Joint and Muscular Pain				
CAPSAICIN				
Crm 0.025% - Special Authority see SA1289 below - Retail				
pharmacy	9.75 4	5 g O	P 🗸	Zostrix
⇒SA1289 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid	without further rene	wal u	nless notif	ied where the patient has
osteoarthritis that is not responsive to paracetamol and oral non-s				
Antirheumatoid Agents				
HYDROXYCHLOROQUINE – Subsidy by endorsement				
Subsidised only if prescribed for rheumatoid arthritis, systemic	or discoid lunus ar	vthom	iatoelle m	alaria troatment or
suppression, relevant dermatological conditions (cutaneous for				
mucosal ulceration)*, sarcoidosis (pulmonary and non-pulmor			,	
Pharmacists may annotate the prescription as endorsed wher				
hydroxychloroguine. Note: Indication marked with a * is an u			p	
* Tab 200 mg		100	1	Plaquenil
LEFLUNOMIDE				
Tab 10 mg	6.00	30	1	Arava
Tab 20 mg		30		Arava
ÿ		00	•	<u>niuvu</u>
PENICILLAMINE	67.00	100	,	D. Damamina
Tab 125 mg		100		D-Penamine
Tab 250 mg	110.12	100	•	D-Penamine
Drugs Affecting Bone Metabolism				
Alendronate for Osteoporosis				
ALENDRONATE SODIUM				
* Tab 70 mg	2.44	4	/	Fosamax
<u> </u>				

•		•	
ALE	ENDRONATE SODIUM WITH COLECALCIFEROL		
*	Tab 70 mg with colecalciferol 5,600 iu1.51	4	✓ Fosamax Plus

Other Treatments

⇒SA1777 Special Authority for Subsidy

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

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

continued...

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 (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

PAMIDRONA	LE 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		1	✓ Pamisol
RA	LOXIFENE HYDROCHLORIDE – Special Authority see SA1779 or	n the next page -	- Retail pha	ırmacy
*	Tab 60 mg	53.76	28	✓ Evista

Subsidy (Manufacturer's Price) \$ Pe

Subsidised Per 🗸

Fully

Brand or Generic Manufacturer

⇒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
- 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

⇒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;

Subsidy	Fully		Brand or
(Manufacturer's Price)	Subsidised		Generic
\$	Per	1	

continued...

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.

ZOLEDRONIC ACID

Inj 0.05 mg per ml, 100 ml, vial - Special Authority see

⇒SA1780 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

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	<u></u>	Per		Manufacturer

continued...

- 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:
 - 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 glucocorticosteriod 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.

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 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

Subsidy (Manufacturer's Price)	Subsid	Fully dised	Brand or Generic
 \$	Per	•	Manufacturer

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- -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 guantified 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 \$29
Tab 100 mg	13.50	30	✓ Desuric S29
			✓ Urinorm S29
	45.00	100	 Benzbromaron AL
			100 \$29

⇒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	10.06	100	✓ Colgout
FEBUXOSTAT - Special Authority see SA2054 below - R			
Brand switch fee payable (Pharmacode 2621967) - see	e page 240 for details		
Tab 80 mg	20.00	28	✓ Febuxostat
•			multichem
Tab 120 mg	20.00	28	✓ Febuxostat
v			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 and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose: or
 - 2.3 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note); or
 - 2.4 The patient has previously had an initial Special Authority approval for benzbromarone for treatment of gout...

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

continued...

Initial application — (Tumour lysis syndrome) only from a haematologist or oncologist. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient is scheduled to receive cancer therapy carrying an intermediate or high risk of tumour lysis syndrome; and
- 2 Patient has a documented history of allopurinol intolerance.

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

✓ Probenecid-AFT 100

Muscle Relaxants

RΑ			

Tab 10 mg	4.20	100	•	Pacifen
Inj 0.05 mg per ml, 1 ml ampoule - Subsidy by	endorsement11.55	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 ✓ 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.

DANTROI FNF

Cap 25 mg	97.50	100	Dantrium
			✓ Dantrium S29 S29
Cap 50 mg	77.00	100	✓ Dantrium
ORPHENADRINE CITRATE			
Tab 100 mg	20.76	100	✓ Norflex

Subsidy (Manufacturer's Price)

Fully Subsidised Per

Brand or Generic Manufacturer

of

Agents for Parkinsonism and Related Disorders

Dopamine Agonists and Related Agents	Dopamine	Agonists a	ind Related	Agents
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Dopamine Agonists and Related Agents			
AMANTADINE HYDROCHLORIDE	20.04		
▲ Cap 100 mg	38.24	60	✓ Symmetrel
APOMORPHINE HYDROCHLORIDE		_	
▲ Inj 10 mg per ml, 2 ml ampoule		5	✓ <u>Movapo</u>
▲ Inj 10 mg per ml, 5 ml ampoule	121.84	5	✓ Movapo
BROMOCRIPTINE MESYLATE – Subsidy by endorsement Subsidy by endorsement – Subsidised for patients who were prescription is endorsed accordingly. Pharmacists may annot prior dispensing of bromocriptine mesylate.			
* Tab 2.5 mg	11.70	30	✓ Parlodel S29
(Parlodel S29 Tab 2.5 mg to be delisted 1 September 2022)			
ENTACAPONE			
▲ Tab 200 mg	18.04	100	✓ Comtan
•	22.00		✓ Entapone
Comtan to be Principal Supply on 1 April 2022			
(Entapone Tab 200 mg to be delisted 1 April 2022)			
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		100	Madopar 62.5
* Cap 100 mg with benserazide 25 mg		100	✓ Madopar 125
* Cap long-acting 100 mg with benserazide 25 mg		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		100	✓ <u>Sinemet</u>
* Tab long-acting 200 mg with carbidopa 50 mg		100	✓ Sinemet CR
* Tab 250 mg with carbidopa 25 mg	38.39	100	✓ Sinemet
PRAMIPEXOLE HYDROCHLORIDE			
▲ Tab 0.25 mg	6.12	100	✓ Ramipex
▲ Tab 1 mg	20.73	100	✓ Ramipex
RASAGILINE			
* Tab 1 mg	53.50	30	✓ Azilect S29
ROPINIROLE HYDROCHLORIDE			
▲ Tab 0.25 mg	2.85	84	✓ Ropin
	3.39	100	✓ Mylan S29
▲ Tab 1 mg		84	✓ Ropin
•	4.70	100	✓ Mylan S29
▲ Tab 2 mg		84	✓ Ropin
▲ Tab 5 mg		84	✓ Ropin
•		-	

				NEN	VOUS SYSTEM
		Subsidy (Manufacturer's Price) \$	Sub Per	Fully osidised	Brand or Generic Manufacturer
	LEGILINE HYDROCHLORIDE – Subsidy by endorsement Subsidy by endorsement – Subsidised for patients who were prescription is endorsed accordingly. Pharmacists may anno prior dispensing of selegiline hydrochloride.	otate the prescription a	as endors	sed where	e there exists a record of
*	Tab 5 mg	48.00	100		po-Selegiline S29 829 depryl 829
(Ap	no-Selegiline S29 S29 Tab 5 mg to be delisted 1 April 2022)	40.00		· Li	ucpi yi 🚾
٠,	LCAPONE				
•	Tab 100 mg	152.38	100	✓ Ta	asmar
A	nticholinergics				
BE	NZATROPINE MESYLATE				
	Tab 2 mg		60 5		enztrop nebra
	a) Up to 10 inj available on a PSO b) Only on a PSO	95.00	5	▼ <u>F1</u>	iebia
PR	OCYCLIDINE HYDROCHLORIDE				
	Tab 5 mg	7.40	100	✓ Ke	emadrin
A	gents for Essential Tremor, Chorea and Relate	ed Disorders			
RIL	UZOLE - Special Authority see SA1403 below - Retail pharm	nacy			
	Wastage claimable Tab 50 mg	130.00	56	√ Ri	ilutek
>	SA1403 Special Authority for Subsidy		00	- <u>- 111</u>	<u>iuton</u>
Init	tial application only from a neurologist or respiratory specialis	t. Approvals valid for	r 6 month	s for app	lications meeting the
	owing criteria:				
All	of the following: 1 The patient has amyotrophic lateral sclerosis with disease	duration of 5 years o	r loce: or	nd	
	2 The patient has at least 60 percent of predicted forced vita3 The patient has not undergone a tracheostomy; and	,	,		nitial application; 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				
Po	5.3 The patient is able to swallow. newal from any relevant practitioner. Approvals valid for 18 m	anthe for applications	nootine	the follo	wing critoria:
	of the following:	ionins ioi applications	, meening	j ilie iolio	wing cinteria.
	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; or3.2 The patient is able to use upper limbs; or				
	3.3 The patient is able to swallow.				
TE	TRABENAZINE				

Tab 25 mg91.10

✓ Motetis

112

	Subsidy	Fully	/ Brand or
	(Manufacturer's Price)) Subsidised Per ✓	
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 a Gel 2%, 11 ml urethral syringe — Subsidy by endorsement			endorsed accordingly. Instillagel Lido
a) Up to 5 each available on a PSOb) Subsidised only if prescribed for urethral, cervical or accordingly.	rectal administration	and the prescrip	otion is endorsed
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE			
Oral (gel) soln 2%			Mucosoothe
Inj 1%, 5 ml ampoule - Up to 25 inj available on a PSO			Lidocaine-Baxter
	17.50 (35.00)	50	Xylocaine
Inj 2%, 5 ml ampoule - Up to 5 inj available on a PSO		25	Lidocaine-Baxter
Inj 1%, 20 ml ampoule - Up to 5 inj available on a PSO		5	
	(20.00)		Xylocaine
Inj 1%, 20 ml vial – Up to 5 inj available on a PSO Inj 2%, 20 ml vial – Up to 5 inj available on a PSO			Lidocaine-Claris Lidocaine-Baxter
111 2%, 20 111 viai – Op to 5 111 available on a F30	0.45		Lidocaine-Baxter
(Lidocaine-Claris Inj 2%, 20 ml vial to be delisted 1 June 2022)			
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 PSOb) Subsidised only if prescribed for urethral or cervical a	administration and th	e prescription is	endorsed accordingly.
Topical Local Anaesthetics			
⇒SA0906 Special Authority for Subsidy			
Initial application from any relevant practitioner. Approvals valid	d for 2 years where t	he patient is a c	hild with a chronic medical
condition requiring frequent injections or venepuncture.			
Renewal from any relevant practitioner. Approvals valid for 2 ye benefiting from treatment.			propriate and the patient is
LIDOCAINE [LIGNOCAINE] – Special Authority see \$A0906 abo		,	LIMANA
Crm 4%		- 9	LMX4 LMX4
LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE - Special Auth		•	
Crm 2.5% with prilocaine 2.5%			EMLA
Crm 2.5% with prilocaine 2.5% (5 g tubes)			EMLA
Analgesics			
For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 1	age 110		
Non-opioid Analgesics			
ASPIRIN			

100

✓ Ethics Aspirin

* Tab dispersible 300 mg - Up to 30 tab available on a PSO......4.50

Brand or

Fully

	(Manufacturer's F		sidised Generic
OADOMONI O LITTU I	\$	Per	✓ Manufacturer
CAPSAICIN – Subsidy by endorsement Subsidised only if prescribed for post-herpetic neuralgia or	diahatic narinhara	ıl nauronathy ai	nd the prescription is endorsed
accordingly.	uiabelic peripriera	ii neuropairiy ai	nd the prescription is endorsed
Crm 0.075%	11.95	45 g OP	✓ Zostrix HP
	15.83	57 g OP	✓ Rugby Capsaicin
			Topical
			Cream S29
NEFOPAM HYDROCHLORIDE			
Tab 30 mg	23.40	90	✓ Acupan
PARACETAMOL			
Tab 500 mg - blister pack	19.75	1,000	✓ Pacimol
a) Maximum of 300 tab per prescription; can be waive	d by endorsement	t	
b) Up to 30 tab available on a PSO			
c)			
Subsidy by endorsement for higher quantities			
regular daily dosing for one month or greater, annotate the prescription as endorsed where			
Maximum of 100 tab per dispensing for non-e			
(for non-endorsed patients), then dispense in			
Tab 500 mg - bottle pack — Maximum of 300 tab per	opout dioponomig	o not oxocount	g 100 tab per dioperionig.
prescription; can be waived by endorsement	17.92	1,000	✓ Noumed
			Paracetamol
1) Subsidy by endorsement for higher quantities is a	vailable for patier	nts with long ter	rm conditions who require regular
daily dosing for one month or greater, and the pre	scription is annot	ated according	ly. Pharmacists may annotate the
prescription as endorsed where dispensing histor			
Maximum of 100 tab per dispensing for non-endo			
non-endorsed patients), then dispense in repeat of	dispensings not ex	ceeding 100 ta	ab per dispensing.
			4-
* Oral liq 120 mg per 5 ml	5.45	1,000 ml	✓ Paracare
a) Up to 200 ml available on a PSO			
b) Not in combination	6.05	1 000 ml	A Davagere Davible
* Oral liq 250 mg per 5 ml	6.25	1,000 ml	✓ <u>Paracare Double</u> Strength
a) Up to 100 ml available on a PSO			Strength
b) Not in combination			
* Suppos 125 mg	3 59	10	✓ Gacet
* Suppos 250 mg		10	✓ Gacet
* Suppos 500 mg		50	✓ Gacet
Opioid Analgesics			
CODEINE PHOSPHATE – Safety medicine; prescriber may de	termine dispensin	a frequency	
Tab 15 mg		100	✓ PSM
T-1: 00	7.45	400	4 POI

100

100

60

/ PSM

✓ PSM

✓ DHC Continus

Subsidy

DIHYDROCODEINE TARTRATE

Tab 60 mg14.25

Tab long-acting 60 mg......8.60

	Subsidy (Manufacturer's Price)		Fully Subsidised	I Generic
	\$	Per		Manufacturer
FENTANYL				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing fr				
Inj 50 mcg per ml, 2 ml ampoule		10	•	Boucher and Muir
Boucher and Muir to be Principal Supply on 1 April 2022		40	,	
Inj 50 mcg per ml, 10 ml ampoule		10	•	Boucher and Muir
Boucher and Muir to be Principal Supply on 1 April 2022		_	,	F
Patch 12.5 mcg per hour		5		Fentanyl Sandoz
Patch 25 mcg per hour		5		Fentanyl Sandoz
Patch 50 mcg per hour		5		Fentanyl Sandoz
Patch 75 mcg per hour		5		Fentanyl Sandoz
Patch 100 mcg per hour	18.59	5	•	Fentanyl Sandoz
METHADONE HYDROCHLORIDE				
 b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing fr d) Extemporaneously compounded methadone will only be (methadone powder, not methadone tablets). e) For methadone hydrochloride oral liquid refer Standard F Tab 5 mg 	reimbursed at the rate formulae, page 242	e of th	·	st form available Methatabs
Oral liq 2 mg per ml		200 m		Biodone
Oral lig 5 mg per ml		200 m		Biodone Forte
Oral lig 10 mg per ml		200 m		Biodone Extra Forte
Inj 10 mg per ml, 1 ml		10		AFT
MORPHINE HYDROCHLORIDE				
a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing fr	eguency			
Oral lig 1 mg per ml	, ,	200 m	nl 🗸	RA-Morph
Oral liq 2 mg per ml	16.24	200 m		RA-Morph
Oral lig 5 mg per ml	19.44	200 m	nl 🗸	Ordine \$29
			1	RA-Morph
Oral lig 10 mg per ml	27.74	200 m		Ordine S29
1	=			DA Marris

✓ RA-Morph

NERVOUS SYSTEM

Sulphate

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic Manufacturer	
IORPHINE SULPHATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing fre	quency			
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 PS	O6.99	5	✓ DBL Morphine	
			Sulphate	
Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a P	SO5.61	5	✓ DBL Morphine Sulphate	
Inj 15 mg per ml, 1 ml ampoule - Up to 5 inj available on a P	SO7.08	5	✓ DBL Morphine Sulphate	
Inj 30 mg per ml, 1 ml ampoule - Up to 5 inj available on a P	SO7.28	5	✓ DBL Morphine	

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
OXYCODONE HYDROCHLORIDE				
a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing fr	requency			
Tab controlled-release 5 mg	2.69 3.01	20 28		Oxycodone Sandoz Oxycodone Sandoz S29 S29
Oxycodone Sandoz to be Principal Supply on 1 June 20 Tab controlled-release 10 mg		20	,	Oxycodone Sandoz
Tab controlled release to mg	3.23	30		Oxycodone Sandoz S29 S29
	5.38	50	✓	Oxycodone Sandoz S29 S29
	10.75	100	✓	Oxycodone Sandoz S29 S29
Oxycodone Sandoz to be Principal Supply on 1 June 20	11.50 022	28	✓	OxyContin
Tab controlled-release 20 mg	3.49 5.38	20 50		Oxycodone Sandoz Oxycodone Sandoz S29 S29
	10.75	100	✓	Oxycodone Sandoz S29 S29
Oxycodone Sandoz to be Principal Supply on 1 June 20	13.25)22	28	✓	OxyContin
Tab controlled-release 40 mg Oxycodone Sandoz to be Principal Supply on 1 June 20)22	20		Oxycodone Sandoz
Tab controlled-release 80 mg Oxycodone Sandoz to be Principal Supply on 1 June 20)22	20		Oxycodone Sandoz
Cap immediate release 5 mg		20 20		OxyNorm OxyNorm
Cap immediate-release 10 mg		20		OxyNorm
Cap immediate-release 20 mg Oral liq 5 mg per 5 ml		250 m		OxyNorm
Inj 10 mg per ml, 1 ml ampoule		5		Hameln
ing to mg por mi, i mi ampodio	7.28	Ü		OxyNorm
Inj 10 mg per ml, 2 ml ampoule		5		Hameln
,	14.36	·		OxyNorm
Inj 50 mg per ml, 1 ml ampoule		5	✓	Hameln OxyNorm
(Oxycodone Sandoz S29 S29 Tab controlled-release 5 mg to b	e delisted 1 June 202	2)		
(Oxycodone Sandoz S29 S29 Tab controlled-release 10 mg to				
(Oxycodone Sandoz S29 S29 Tab controlled-release 10 mg to	be delisted 1 June 20	22)		
(Oxycodone Sandoz S29 \$29 Tab controlled-release 10 mg to (OxyContin Tab controlled-release 10 mg to be delisted 1 June 2	be delisted 1 June 20	,		
(Oxycodone Sandoz S29 S29 Tab controlled-release 20 mg to	be delisted 1 June 20	22)		
(Oxycodone Sandoz S29 S29 Tab controlled-release 20 mg to (OxyContin Tab controlled-release 20 mg to be delisted 1 June (OxyNorm Inj 10 mg per ml, 1 ml ampoule to be delisted 1 July 2 (OxyNorm Inj 10 mg per ml, 2 ml ampoule to be delisted 1 July 2 (OxyNorm Inj 50 mg per ml, 1 ml ampoule to be delisted 1 July 2 (OxyNorm Inj 50 mg per ml, 1 ml ampoule to be delisted 1 July 2	be delisted 1 June 20. 2022) 2022) 2022)	,		

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
PARACETAMOL WITH CODEINE - Safety medicine; prescriber * Tab paracetamol 500 mg with codeine phosphate 8 mg		ensing 1,000		y Paracetamol + Codeine (Relieve)
PETHIDINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing fre	quency			
Tab 50 mg		10		<u>PSM</u>
Inj 50 mg per ml, 1 ml ampoule - Up to 5 inj available on a P	SO29.88	5	•	DBL Pethidine
				Hydrochloride
Inj 50 mg per ml, 2 ml ampoule - Up to 5 inj available on a P	SO30.72	5	•	DBL Pethidine Hydrochloride
TRAMADOL HYDROCHLORIDE				
Tab sustained-release 100 mg	1.52	20	1	Tramal SR 100
Tab sustained-release 150 mg		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 di	ispensing 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				
a) Brand switch fee payable (Pharmacode 2630915) - see pa				
b) Safety medicine; prescriber may determine dispensing fre	quency			
Tab 10 mg		30		Clomipramine Teva
Tab 25 mg	11.99	30	/	Clomipramine Teva
DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE - Subsidy by end	dorsement			
a) Safety medicine; prescriber may determine dispensing fre	quency			
b) Subsidy by endorsement – Subsidised for patients who we				
2019 and the prescription is endorsed accordingly. Pharm		the p	rescriptio	n as endorsed where there
exists a record of prior dispensing of dosulepin [dothiepin]	•		_	
Tab 75 mg		30		Dosulepin Mylan
Cap 25 mg	7.83	50	•	Dosulepin
				Mylan S29
IMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber i	,	•		
Tab 10 mg		50		Tofranil
Tob 05 mg	10.96	100 50		Tofranil Tofranil
Tab 25 mg				
NORTRIPTYLINE HYDROCHLORIDE - Safety medicine; prescr				
Tab 10 mg		100		Norpress
Tab 25 mg	5.98	180	•	Norpress

	Subsidy (Manufacturer's Price) \$	Fu Subsidise Per	•
Monoamine-Oxidase Inhibitors (MAOIs) - Non S	Selective		
TRANYLCYPROMINE SULPHATE Tab 10 mg	12.85 22.94 45.88 96.00	50 100	Parnate S29 S29 Parnate Parnate S29 S29 Parnate S29 S29
Monoamine-Oxidase Type A Inhibitors			
MOCLOBEMIDE * Tab 150 mg * Tab 300 mg			Aurorix Aurorix
Selective Serotonin Reuptake Inhibitors			
CITALOPRAM HYDROBROMIDE * Tab 20 mg ESCITALOPRAM	1.91	84	PSM Citalopram
* Tab 10 mg	1.07	28	Escitalopram (Ethica)
₭ Tab 20 mg	1.92	28	(Ethics) Escitalopram (Ethics)
FLUOXETINE HYDROCHLORIDE Tab dispersible 20 mg, scored — Subsidy by endorsement Subsidised by endorsement When prescribed for a patient who cannot swallov accordingly; or When prescribed in a daily dose that is not a multiendorsed. Note: Tablets should be combined with	wwhole tablets or caps	sules and the	cription is deemed to be
Cap 20 mg	2.91	84	✓ Fluox
PAROXETINE * Tab 20 mg	3.61	90	Loxamine
SERTRALINE * Tab 50 mg	0.92		✓ <u>Setrona</u> ✓ Setrona AU
* Tab 100 mg	1.61		<u>Setrona</u>
Other Antidepressants			
/IRTAZAPINE Tab 30 mg Tab 45 mg			Noumed Noumed
/ENLAFAXINE * Cap 37.5 mg * Cap 75 mg	8.11	84	Enlafax XR Enlafax XR
* Cap 150 mg	11.16	84	Enlafax XR

			NERVOUS SYSTEM
	Subsidy (Manufacturer's Price) \$	Subs Per	Fully Brand or idised Generic ✓ Manufacturer
Antiepilepsy Drugs			
Agents for Control of Status Epilepticus			
DIAZEPAM – Safety medicine; prescriber may determine dispen Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement a) Up to 5 inj available on a PSO b) Only on a PSO		5	✓ Hospira
c) PSO must be endorsed "not for anaesthetic procedur Rectal tubes 5 mg - Up to 5 tube available on a PSO PHENYTOIN SODIUM		5	✓ Stesolid
* 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 * Tab long-acting 200 mg * Tab 400 mg * Tab long-acting 400 mg * Oral liq 20 mg per ml	16.98 34.58 39.17	100 100 100 100 250 ml	✓ Tegretol ✓ Tegretol CR ✓ Tegretol ✓ Tegretol CR ✓ Tegretol CR ✓ Tegretol
CLOBAZAM – Safety medicine; prescriber may determine dispertable 10 mg	9.12	50	✓ Frisium
Oral drops 2.5 mg per ml ETHOSUXIMIDE Cap 250 mg	7.38 1	0 ml OP 100 200 ml	✓ Rivotril ✓ Zarontin ✓ Zarontin
Oral liq 250 mg per 5 ml		200 IIII	Zaronun
Note: Not subsidised in combination with subsidised pregab * Cap 100 mg * Cap 300 mg * Cap 400 mg LACCOMMEDE: Special Authority and SA1125 below. Partial of	6.45 8.45 10.26	100 100 100	✓ Nupentin ✓ Nupentin ✓ Nupentin
LACOSAMIDE – Special Authority see SA1125 below – Retail pl	namacy		

⇒SA1125 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

200.24

300.40

1 Patient has partial-onset epilepsy; and

▲ Tab 50 mg25.04

▲ Tab 100 mg50.06

Tab 150 mg75.10

continued...

✓ Vimpat

✓ Vimpat ✓ Vimpat

✓ Vimpat ✓ Vimpat

✓ Vimpat

14

14

56

14

56

Subsidy		Fully	Brand or
(Manufacturer's Price)	5	Subsidised	Generic
\$	Per	/	Manufacturer

continued...

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.

LAMOTRIGINE			
▲ Tab dispersible 2 mg	55.00	30	✓ Lamictal
▲ Tab dispersible 5 mg		30	✓ Lamictal
* Tab dispersible 25 mg		56	✓ Logem
* Tab dispersible 50 mg		56	✓ Logem
* Tab dispersible 100 mg		56	✓ Logem
LEVETIRACETAM			
Tab 250 mg	4 99	60	✓ Everet
Tab 500 mg		60	✓ Everet
Tab 750 mg		60	✓ Everet
Tab 1,000 mg		60	✓ Everet
Oral lig 100 mg per ml		300 ml OP	✓ Levetiracetam-AFT
PHENOBARBITONE	1 1.7 0	000 1111 01	
	2000 040		
For phenobarbitone oral liquid refer Standard Formulae,		500	✓ PSM
* Tab 30 mg		500	✓ PSM
* Tab 30 mg	40.00	500	♥ PSIVI
PHENYTOIN SODIUM			
* Tab 50 mg		200	✓ Dilantin Infatab
Cap 30 mg		200	✓ Dilantin
Cap 100 mg		200	✓ Dilantin
* Oral liq 30 mg per 5 ml	22.03	500 ml	✓ Dilantin
PREGABALIN			
Note: Not subsidised in combination with subsidised ga	bapentin		
* 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
SODIUM VALPROATE			
Tab 100 mg	12.65	100	✓ Epilim Crushable
Tab 200 mg EC		100	✓ Epilim
Tab 500 mg EC		100	✓ Epilim
* Oral lig 200 mg per 5 ml		300 ml	✓ Epilim S/F Liquid
The stating 200 mg per o mil	20.40	000 1111	✓ Epilim Syrup
* Inj 100 mg per ml, 4 ml	41 50	1	✓ Epilim IV
• III 100 III9 pci IIII, 4 IIII		'	- Lhiiii i

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
STIRIPENTOL - Special Authority see SA1330 below - Retail pl	narmacy			
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
- 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

VIGABATRIN – Special Authority see SA2088 below – Retai Tab 500 mg		100	✓ Sabril
Sprinkle cap 25 mg		60	✓ Topamax
Sprinkle cap 15 mg	20.84	60	✓ Topamax
	129.85		✓ Topamax
v			✓ Topiramate Actavis
▲ Tab 200 mg	55.19	60	Arrow-Topiramate
	75.25		✓ Topamax
			✓ Topiramate Actavis
▲ Tab 100 mg	31.99	60	Arrow-Topiramate
	44.26		✓ Topamax
			Topiramate Actavis
▲ Tab 50 mg	18.81	60	Arrow-Topiramate
	26.04		✓ Topamax
			Topiramate Actavis
▲ Tab 25 mg	11.07	60	Arrow-Topiramate

⇒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 Fither:
 - 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

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

continued...

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
- - 2.1 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

RIZATRIPTAN			
Tab orodispersible 10 mg	3.65	30	✓ Rizamelt
SUMATRIPTAN			
Tab 50 mg	14.41	90	✓ Sumagran
Tab 100 mg	22.68	90	✓ Sumagran
Inj 12 mg per ml, 0.5 ml prefilled pen - Maximum of 10 inj per			
prescription	34.00	2 OP	✓ <u>Imigran</u>

Prophylaxis of Migraine

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 50

PIZOTIFEN

100 ✓ Sandomigran

Antinausea and Vertigo Agents

For Antispasmodics refer to ALIMENTARY TRACT, page 8

APREPITANT – Special Authority see SA0987 below – Retail pharmacy 3 OP ✓ Emend Tri-Pack

⇒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	3.88	84	✓ Vergo 16
v	4.62	100	✓ Serc
(Vergo 16 Tab 16 mg to be delisted 1 July 2022)			
CYCLIZINE HYDROCHLORIDE			
Tab 50 mg	0.49	10	✓ Nausicalm

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic Manufacturer
CYCLIZINE LACTATE			
Inj 50 mg per ml, 1 ml	21.53	10	✓ <u>Hameln</u>
DOMPERIDONE			
* Tab 10 mg	2.85	100	✓ Pharmacy Health
HYOSCINE HYDROBROMIDE			
* Inj 400 mcg per ml, 1 ml ampoule	93.00	10	✓ Martindale S29
Patch 1.5 mg - Special Authority see SA1998 below - Retail			
pharmacy		2	✓ Scopoderm TTS
 SA1998 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid Either: 1 Control of intractable nausea, vomiting, or inability to swall where the patient cannot tolerate or does not adequately r 2 Control of clozapine-induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where trials of the control of clozapine induced hypersalivation where the control of	low saliva in the treat	ment ause	of malignancy or chronic disease a agents; or
ineffective. Renewal from any relevant practitioner. Approvals valid for 1 year benefiting from treatment.			
METOCLOPRAMIDE HYDROCHLORIDE			
* Tab 10 mg - Up to 30 tab available on a PSO		100	✓ Metoclopramide Actavis 10
* Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PS	SO9.50	10	✓ <u>Pfizer</u>
ONDANSETRON			_
* Tab 4 mg		50	Onrex
* Tab disp 4 mg - Up to 10 tab available on a PSO		10	✓ Ondansetron ODT-DRLA
* Tab 8 mg		50	✓ <u>Onrex</u>
* Tab disp 8 mg - Up to 10 tab available on a PSO	1.13	10	✓ <u>Ondansetron</u> <u>ODT-DRLA</u>
PROCHLORPERAZINE			
* Tab 3 mg buccal		50	_
Nr. Tab Farm Hall 200 tab and Habitana a BOO	(30.00)	050	Buccastem
* Tab 5 mg - Up to 30 tab available on a PSO * Ini 12.5 mg per ml. 1 ml - Up to 5 ini available on a PSO		250 10	 ✓ <u>Nausafix</u> ✓ Stemetil
,	25.01	10	• Stemetii
Antipsychotics			
General	i fu		
AMISULPRIDE – Safety medicine; prescriber may determine dis Tab 100 mg		30	✓ <u>Sulprix</u>
Tab 100 Hig	17.16	100	✓ <u>Sulprix</u> ✓ Amisulpride
	17.110		Mylan S29
Tab 200 mg	14.96	60	✓ Sulprix
Tab 400 mg		60	✓ Sulprix
ARIPIPRAZOLE – Safety medicine; prescriber may determine di			
Tab 5 mg		30	✓ Aripiprazole Sandoz
Tab 10 mg		30	✓ Aripiprazole Sandoz
Tab 15 mg		30	✓ Aripiprazole Sandoz
Tab 20 mg		30	✓ Aripiprazole Sandoz
Tab 30 mg		30	✓ Aripiprazole Sandoz

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

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	
	\$	Per	✓	Manufacturer
CHLORPROMAZINE HYDROCHLORIDE - Safety medicine	e: prescriber may determ	ine dis	pensina fr	eguency
Tab 10 mg – Up to 30 tab available on a PSO		100		Largactil
Tab 25 mg - Up to 30 tab available on a PSO		100		Largactil
Tab 100 mg - Up to 30 tab available on a PSO		100		Largactil
Inj 25 mg per ml, 2 ml - Up to 5 inj available on a PSO		10		Largactil
LOZAPINE – Hospital pharmacy [HP4]				<u></u>
Safety medicine; prescriber may determine dispensing fr	roguenov			
Tab 25 mg	' '	50	./	Clozaril
1au 25 mg	6.69	50		Clopine
	11.36	100		Clozaril
	13.37	100		Clopine
Tab 50 mg		50		Clopine
1 ab 50 mg	17.33	100		Clopine
Tab 100 mg		50		Clozaril
Tab 100 mg	17.33	50		Clopine
	29.45	100		Clozaril
		100	_	
Tab 200 mg	34.65	50	_	Clopine
1 ab 200 mg	69.30	100		Clopine Clopine
Cuppopoian EO ma nor ml				Clopine
Suspension 50 mg per ml		100 m		Versacloz
Nanina Cuananaian FO ma nor ml to be delicted 1 April 200	67.62		•	versacioz
Clopine Suspension 50 mg per ml to be delisted 1 April 2022	•			
ALOPERIDOL – Safety medicine; prescriber may determin			_	_
Tab 500 mcg - Up to 30 tab available on a PSO		100		Serenace
Tab 1.5 mg - Up to 30 tab available on a PSO		100	_	Serenace
Tab 5 mg - Up to 30 tab available on a PSO		50	_	Serenace
	29.72	100		<u>Serenace</u>
Oral liq 2 mg per ml - Up to 200 ml available on a PSO.		100 m		<u>Serenace</u>
Inj 5 mg per ml, 1 ml ampoule - Up to 5 inj available on	a PSO21.55	10	✓	<u>Serenace</u>
EVOMEPROMAZINE - Safety medicine; prescriber may d	etermine dispensing free	uency	,	
Tab 25 mg (33.8 mg as a maleate)		100		Nozinan (Swiss)
Tab 25 mg as a maleate		100		Nozinan `
Tab 100 mg (135 mg as a maleate)		100	✓	Nozinan (Swiss)
Tab 100 mg as a maleate		100	_	Nozinan `
EVOMEPROMAZINE HYDROCHLORIDE – Safety medicir		nina d	ienoneina	frequency
Inj 25 mg per ml, 1 ml ampoule		10		Nozinan
				IVOZIIIAII
THIUM CARBONATE – Safety medicine; prescriber may d				
Tab long-acting 400 mg		100		Priadel
Cap 250 mg	9.42	100	•	Douglas
LANZAPINE - 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		28		Zypine
Tab orodispersible 10 mg		28		Zypine ODT
ERICYAZINE - Safety medicine; prescriber may determine				
Tab 2.5 mg	, , ,	84	1	Neulactil
I UD E.V IIIY	12.49	100		Neulactil
Tab 10 mg		84		Neulactil
Tab To my	44.45	100		Neulactil
	44.40	100	•	INCUIACUI

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
QUETIAPINE – Safety medicine; prescriber may determine disp	ensina frequency			
Tab 25 mg		90	1	Quetapel
Tab 100 mg		90	1	Quetapel
Tab 200 mg		90	1	Quetapel
Tab 300 mg	12.86	90	✓	Quetapel
RISPERIDONE - Safety medicine; prescriber may determine di	spensing frequency			
Tab 0.5 mg		60	1	Risperidone (Teva)
Tab 1 mg		60	✓	Risperidone (Teva)
Tab 2 mg		60	1	Risperidone (Teva)
Tab 3 mg	2.50	60	1	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 dis	spensing frequency			
Cap 20 mg	14.50	60	✓	Zusdone
Cap 40 mg	24.70	60	1	Zusdone
Cap 60 mg	33.80	60	✓	Zusdone
Cap 80 mg	39.70	60	•	Zusdone
ZUCLOPENTHIXOL HYDROCHLORIDE - Safety medicine; pre	escriber may determin	e disp	ensing fre	quency
Tab 10 mg	31.45	100	✓	Clopixol

Depot Injections

FLUPENTHIXOL DECANOATE - Safety medicine; prescriber may d	etermine dispensi	ng frequenc	у
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 de	termine dispensir	g frequency	1
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 S29
OLANZAPINE - Special Authority see SA1428 below - Retail pharm	acy		
Safety medicine; prescriber may determine dispensing frequency	,		
Inj 210 mg vial		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.

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	(Manufacturer's Price)		ubsidised ✓	Generic Manufacturer
PALIPERIDONE – Special Authority see SA1429 below – Retail	pharmacy			
Safety medicine; prescriber may determine dispensing frequ	ency			
Inj 25 mg syringe	194.25	1	✓ In	vega Sustenna
Inj 50 mg syringe	271.95	1	✓ In	vega Sustenna
Inj 75 mg syringe	357.42	1	✓ In	vega Sustenna
Inj 100 mg syringe	435.12	1	✓ In	vega Sustenna
Inj 150 mg syringe		1	🗸 Ir	vega Sustenna

Subsidy

Fully

Brand or

⇒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 f	requency		
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 trialing 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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
Anxiolytics				
BUSPIRONE HYDROCHLORIDE				
* Tab 5 mg	18.50	100	✓	Buspirone Viatris
•	20.23			Orion
Buspirone Viatris to be Principal Supply on 1 May 2022				
* Tab 10 mg		100		Buspirone Viatris
	13.16		•	Orion
Buspirone Viatris to be Principal Supply on 1 May 2022				
(Orion Tab 5 mg to be delisted 1 May 2022)				
(Orion Tab 10 mg to be delisted 1 May 2022)				
CLONAZEPAM – Safety medicine; prescriber may determine dis				_
Tab 500 mcg		100		Paxam
Tab 2 mg		100	•	Paxam
DIAZEPAM – Safety medicine; prescriber may determine dispen			_	
Tab 2 mg		500		Arrow-Diazepam
Tab 5 mg	73.60	500	•	Arrow-Diazepam
LORAZEPAM – Safety medicine; prescriber may determine disp	0 1 ,		_	
Tab 1 mg		250		<u>Ativan</u>
Tab 2.5 mg	12.50	100	•	<u>Ativan</u>
OXAZEPAM - Safety medicine; prescriber may determine dispe	nsing frequency			
Tab 10 mg	6.17	100		Ox-Pam
Tab 15 mg	8.53	100	/	Ox-Pam
(Ox-Pam Tab 10 mg to be delisted 1 April 2022)				
(Ox-Pam Tab 15 mg to be delisted 1 April 2022)				

Multiple Sclerosis Treatments

⇒SA2051 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) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2 Patients must have Clinically Definite Relapsing multiple sclerosis with or without underlying progression; and
- 3 Patients must have an EDSS score between 0 6.0; and
- 4 Patient has had at least 1 significant relapse of multiple sclerosis in the previous 12 months or 2 significant relapses in the past 24 months; and
- 5 All of the following:
 - 5.1 Each significant relapse must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse, but the neurologist/physician must be satisfied that the clinical features were characteristic); and
 - 5.2 Each significant relapse is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
 - 5.3 Each significant relapse has lasted at least one week and has started at least one month after the onset of a previous relapse; and
 - 5.4 Each significant relapse can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C); and



	Subsidy	Fully	Brand or
(Manufa	acturer's Price)	Subsidised	Generic
	\$ Per	•	Manufacturer

continued...

- 5.5 Either:
 - 5.5.1 Each significant relapse is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or
 - 5.5.2 Each significant relapse is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and
- 6 Evidence of new inflammatory activity on an MR scan within the past 24 months; and
- 7 Any of the following:
 - 7.1 A sign of that new inflammatory activity is a gadolinium enhancing lesion; or
 - 7.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or
 - 7.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or
 - 7.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse that occurred within the last 2 years; or
 - 7.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MR scan.

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier. Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. 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 SA2051 on the previous page - Retail pharmacy

a) Wastana claimahla

a) Wastage claimable		:	
b) Note: Treatment on two or more funded multiple : Cap 120 mg		aneousiy is 14	r not permitted. ✓ Tecfidera
Cap 240 mg		56	✓ Tecfidera
FINGOLIMOD – Special Authority see SA2051 on the pre			· Toondord
a) Wastage claimable	vious page – netail pham	lacy	
b) Note: Treatment on two or more funded multiples	colorosis traatments simult	angouely is	not parmitted
Cap 0.5 mg		28	✓ Gilenya
GLATIRAMER ACETATE – Special Authority see SA205	•		•
Note: Treatment on two or more funded multiple scle			•
Inj 40 mg prefilled syringe		12	✓ Copaxone
INTERFERON BETA-1-ALPHA — Special Authority see S		na – Retail	•
Note: Treatment on two or more funded multiple scle			
Inj 6 million iu prefilled syringe		4	✓ Avonex
Injection 6 million iu per 0.5 ml pen injector		4	Avonex Pen
INTERFERON BETA-1-BETA - Special Authority see SA	2051 on the previous page	e – Retail p	harmacy
Note: Treatment on two or more funded multiple scle	rosis treatments simultane	ously is no	t permitted.
Inj 8 million iu per 1 ml	1,322.89	15	Betaferon
NATALIZUMAB - Special Authority see SA2051 on the p	revious page – Retail phai	macy	
Note: Treatment on two or more funded multiple scle		ously is no	t permitted.
Inj 20 mg per ml, 15 ml vial	1,750.00	1	Tysabri
OCRELIZUMAB - Special Authority see SA2051 on the p	orevious page – Retail pha	rmacy	
Note: Treatment on two or more funded multiple scle		ously is no	•
Inj 30 mg per ml, 10 ml vial	9,346.00	1	Ocrevus

NERVOUS SYSTEM

Subsidy		Fully	Brand or	
(Manufacturer's Price)	9	Subsidised	Generic	
\$	Per	✓	Manufacturer	

TERIFLUNOMIDE - Special Authority see SA2051 on page 135 - Retail pharmacy

- a) Wastage claimable
- b) Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

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 ✓ Circadin

Vigisom to be Principal Supply on 1 April 2022

(Circadin Tab modified-release 2 mg to be delisted 1 April 2022)

⇒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 (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 ✓ Midazolam-Baxter 10 Ini 1 mg per ml. 5 ml plastic ampoule – Up to 10 ini available on a PSO.......17.28 ✓ Pfizer 10 On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only. ✓ Midazolam-Baxter Inj 5 mg per ml, 3 ml ampoule4.50 5 Inj 5 mg per ml, 3 ml plastic ampoule - Up to 5 inj available on a PSO.......13.09 ✓ 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 10 ✓ Max Health S29

⇒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.

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic Manufacturer
EMAZEPAM – Safety medicine; prescriber ma	, , , ,		
Tab 10 mg		25	✓ Normison
RIAZOLAM - 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
OPICLONE - Safety medicine; prescriber may	determine dispensing frequency		
Tab 7.5 mg		500	✓ Zopiclone Actavis
-			_
Stimulants/ADHD Treatments			
TOMOVETIME			
TOMOXETINE	40.44	00	4.100
Cap 10 mg	18.41	28	✓ APO-
			Atomoxetine S29
			✓ Generic Partners
	107.03		✓ Generic Partiters ✓ Strattera
Cap 18 mg		28	✓ Generic Partners
Cap 18 mg	107.03	20	✓ Strattera
Cap 25 mg		28	✓ Generic Partners
Cap 40 mg		28	✓ Generic Partners
Oap 40 mg	107.03	20	✓ Strattera
Cap 60 mg		28	✓ Generic Partners
Cap 80 mg		28	✓ APO-
Oap oo mg	50.45	20	Atomoxetine S29
			Atomoxetine 329
			✓ Generic Partners
Cap 100 mg	58.48	28	✓ APO-
			Atomoxetine S29
			Atomoxetine
			✓ Generic Partners
DEXAMFETAMINE SULFATE - Special Author	rity saa SA1140 balaw - Ratail pharma	CV	
a) Only on a controlled drug form	ity see OAT 149 Delow - netali pilatilla	ю	
	ina diananaina fraguanay		
b) Safety medicine; prescriber may determ		100	✓ PSM
Tab 5 mg	21.00	100	▼ POW

⇒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

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

continued...

applications meeting the following criteria:

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		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		30	✓ Rubifen SR
Tab extended-release 27 mg		30	Methylphenidate ER
· ·			- Teva
Tab extended-release 36 mg	15.50	30	✓ Methylphenidate ER
J			- Teva
Tab extended-release 54 mg	22.25	30	✓ Methylphenidate ER
Tab extenses received a ring.			- 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 Fither:
 - 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



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

continued...

applications meeting the following criteria:

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.

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	58.96	30	Concerta
Tab extended-release 27 mg	65.44	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

NERVOUS SYSTEM

S	Subsidy	Fully	Brand or
(Manufa	acturer's Price) Subsi	dised	Generic
	\$ Per	1	Manufacturer

continued...

hvdrochloride.

Renewal 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 Fither:
 - 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 pharma	су		
Tab 100 mg	29.13	60	✓ Modavigil

⇒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 Fither:
 - 3.1 An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled 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 - Re	etail pharmacy	
Patch 4.6 mg per 24 hour	38.00 30	✓ Rivastigmine Patch
		<u>BNM 5</u>
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	Fully	Brand or
	acturer's Price)	Subsidised	Generic
`	é É		Manufacturer

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

✓ Buprenorphine 28 Naloxone BNM

Tab sublingual 8 mg with naloxone 2 mg53.12 28 ✓ Buprenorphine Naloxone BNM

⇒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);
- 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.

BUPROPION HYDROCHLORIDE

30 Zyban

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
DISULFIRAM Tab 200 mg	236.40	100	1	Antabuse
NALTREXONE HYDROCHLORIDE – Special Authority see SAT		harm 30	•	<u>Naltraccord</u>

⇒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 one of the District Health Boards 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.

provisions in F	art I of Section	on A.
18.14	28	Habitrol
3.94	7	Habitrol
19.95	28	Habitrol
4.52	7	Habitrol
22.86	28	Habitrol
5.18	7	Habitrol
19.18	216	Habitrol
3.20	36	Habitrol
21.02	216	Habitrol
3.24	36	Habitrol
38.21	384	Habitrol
8.64	96	Habitrol
38.21	384	Habitrol
8.64	96	Habitrol
44.17	384	Habitrol
10.01	96	Habitrol
44.17	384	Habitrol
10.01	96	Habitrol
	e provisions in F18.143.9419.954.5222.8619.183.2021.023.2438.218.6444.1710.0144.17	3.94 719.95 284.52 722.86 285.18 719.18 2163.20 3621.02 2163.24 3638.21 3848.64 9638.21 3848.64 9644.17 38410.01 9644.17 384

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)	F Subsidi	ully	Brand or Generic
 \$	Per	√	Manufacturer

⇒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.

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer

Chemotherapeutic Agents

Alkylating Agents

BENDAMUSTINE HYDROCHLORIDE - PCT only - Specialist - Special Authority see SA2046 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

⇒SA2046 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 Either:
 - 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 All of the following:
 - 3.2.1 Patient has relapsed refractory disease following prior chemotherapy; and
 - 3.2.2 The patient has not received prior bendamustine therapy; and
 - 3.2.3 Fither:
 - 3.2.3.1 Both:
 - 3.2.3.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
 - 3.2.3.1.2 Patient has had a rituximab treatment-free interval of 12 months or more: or
 - 3.2.3.2 Bendamustine is to be administered as a 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:

Both:

- 1 Patients have not received a bendamustine regimen within the last 12 months; and
- 2 Fither:
 - 2.1 Both:

Subsidy (Manufacturer's I	Price) Sub	Fully	Brand or Generic	
\$	Per	•	Manufacturer	

continued...

- 2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
- 2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more; or
- 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/m² twice per cycle, for a maximum of four cycles.

Note: Indications marked with * are unapproved indications.

BUSULFAN - PCT - Retail pharmacy-Specialist

bosoci Ait – i o i – Hetali phamacy-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	1,387.00	1	✓ BiCNU
, ,			✓ Bicnu Heritage S29
Inj 100 mg for ECP	1,387.00	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		1	✓ Cisplatin Ebewe
iii, i iiig poi iiii, ioo iii va	29.66	•	✓ DBL Cisplatin
Inj 1 mg for ECP		1 mg	✓ Baxter
CYCLOPHOSPHAMIDE		3	
Tab 50 mg - PCT - Retail pharmacy-Specialist	145.00	50	✓ Cyclonex
Inj 1 g vial – PCT – Retail pharmacy-Specialist		1	✓ Endoxan
ing i g viai i o i i riciaii phamacy opeciaici	127.80	6	✓ Cytoxan
Inj 2 g vial - PCT only - Specialist		1	✓ Endoxan
Inj 1 mg for ECP – PCT only – Specialist		1 mg	✓ Baxter
IFOSFAMIDE – PCT only – Specialist		9	
Inj 1 g	96.00	1	✓ Holoxan
Inj 2 g		1	✓ Holoxan
Inj 1 mg for ECP		1 mg	✓ Baxter
LOMUSTINE – PCT – Retail pharmacy-Specialist		9	-4/101
Cap 10 mg	122 50	20	✓ CeeNU
. •		20	✓ CeeNU ✓ CeeNU
Cap 40 mg	399.15	20	- Ceenu

(M	Subsidy lanufacturer's Price) \$	Subs Per	Fully sidised	
MELPHALAN				
Tab 2 mg - PCT - Retail pharmacy-Specialist	40.70	25	1	Alkeran
Inj 50 mg - PCT only - Specialist	67.80	1	1	Alkeran
			1	Alkeran S29 S29
OXALIPLATIN - PCT only - Specialist				
Inj 100 mg vial	25.01	1	1	Oxaliplatin Actavis 100
	110.00		1	Oxaliplatin Ebewe
Inj 5 mg per ml, 20 ml vial	46.32	1	1	Oxaliplatin Accord
Inj 1 mg for ECP	0.48	1 mg	1	Baxter
THIOTEPA - PCT only - Specialist				
Inj 15 mg vial	CBS	1	1	Bedford S29
, ,			1	Max Health S29
			1	THIO-TEPA S29
				Tepadina S29
Inj 100 mg vial	CBS	1		Max Health \$29
inj 100 mg vidi		'		Tepadina \$29
			•	i chanilla 222
Antimetabolites				
AZACITIDINE - PCT only - Specialist - Special Authority see SA14	167 below			
Inj 100 mg vial		1	•	Azacitidine Dr Reddy's

AZACITIDINE – PCT only – Specialist – Special Autl	nority see SA1467 below		
Inj 100 mg vial	75.06	1	Azacitidine Dr
, ,			Reddy's
	605.00		✓ Vidaza
Inj 1 mg for ECP	0.83	1 mg	✓ Baxter

⇒SA1467 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:

- 1 Any of the following:
 - 1.1 The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic
 - 1.2 The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder);
 - 1.3 The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
- 2 The patient has performance status (WHO/ECOG) grade 0-2; and
- 3 The patient does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and
- 4 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:

- 1 No evidence of disease progression; and
 - 2 The treatment remains appropriate and patient is benefitting from treatment.

	Subsidy		Fully Brand or
(1	Manufacturer's Pric		Subsidised Generic
	\$	Per	✓ 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		1	✓ <u>Calcium Folinate</u> Sandoz
			✓ Calcium Folinate
			Sandoz S29 S29
Inj 50 mg - PCT - Retail pharmacy-Specialist	72 80	10	✓ Leucovorin
ing oo mg 1 or 110tan phamaoy opoolanot		10	Pharmacia S29
Inj 10 mg per ml, 10 ml vial - PCT only - Specialist	9.49	1	✓ Calcium Folinate
ing roting per fill, ro fill vial 1 of only openials			Sandoz
Inj 100 mg - PCT only - Specialist	7.33	1	✓ Calcium Folinate
ing rooming it or only opposition		•	Ebewe
	94.90	10	✓ Leucovorin
	000		Pharmacia S29
Inj 300 mg - PCT only - Specialist	22 51	1	✓ Calcium Folinate
ing ood ing it of only openialist	22.01		Ebewe
	25.14		✓ Leucovorin DBL S29
	25.14		- Leacovoriii BBL
Inj 10 mg per ml, 35 ml vial - PCT only - Specialist	25.14	1	✓ Calcium Folinate
			Sandoz
			✓ Calcium Folinate
			Sandoz S29 S29
Inj 1 g - PCT only - Specialist	67.51	1	✓ Calcium Folinate
Ini 10 man non mel 100 mel viol - BOT autho - Consciolist	70.00		Ebewe
Inj 10 mg per ml, 100 ml vial - PCT only - Specialist	/2.00	1	✓ Calcium Folinate Sandoz
Ini 1 mg for ECD DCT only Changing	0.06	1 ma	
Inj 1 mg for ECP – PCT only – Specialist	0.06	1 mg	✓ Baxter
CAPECITABINE – Retail pharmacy-Specialist	10.00		
Tab 150 mg		60	✓ <u>Capercit</u>
Tab 500 mg	49.00	120	✓ <u>Capercit</u>
CLADRIBINE – PCT only – Specialist			
Inj 1 mg per ml, 10 ml		1	✓ Leustatin
Inj 10 mg for ECP	/49.96	10 mg C	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		1	✓ Pfizer
Inj 1 mg for ECP – PCT only – Specialist		10 mg	•
Inj 100 mg intrathecal syringe for ECP - PCT only - Specialist	80.00	100 mg (OP ✓ Baxter
FLUDARABINE PHOSPHATE	440.00		/ Floring O. J.
Tab 10 mg - PCT - Retail pharmacy-Specialist		20	✓ Fludara Oral
Inj 50 mg vial – PCT only – Specialist		50 mg C	✓ Fludarabine Ebewe P ✓ Baxter
Inj 50 mg for ECP – PCT only – Specialist	1 13.29	50 mg C	JF ▼ Daxief
FLUOROURACIL	40.51		
Inj 50 mg per ml, 20 ml vial – PCT only – Specialist		1	✓ Fluorouracil Accord
Inj 50 mg per ml, 100 ml vial – PCT only – Specialist		100 m	✓ Fluorouracil Accord
Inj 1 mg for ECP – PCT only – Specialist	0.62	100 mg	g ✓ Baxter

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	Subsidised	Generic
	\$	Per	•	Manufacturer
GEMCITABINE HYDROCHLORIDE – PCT only – Specialist				
Inj 1 g, 26.3 ml vial	62.50	1	✓	DBL Gemcitabine
lnj 1 g	15.89	1	✓	Gemcitabine Ebewe
Inj 1 mg for ECP		1 mg	1	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		1	Irinotecan-Rex
Inj 1 mg for ECP	0.54	1 mg	✓	Baxter
MERCAPTOPURINE				
Tab 50 mg - PCT - Retail pharmacy-Specialist	37.00	25	✓	Puri-nethol
Oral suspension 20 mg per ml - Retail pharmacy-Specialist	:-			
Special Authority see SA1725 below		00 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.

ME	THOTREXATE		
*	Tab 2.5 mg - PCT - Retail pharmacy-Specialist9.98	90	✓ <u>Trexate</u>
*	Tab 10 mg - PCT - Retail pharmacy-Specialist33.71	90	✓ <u>Trexate</u>
*	Inj 2.5 mg per ml, 2 ml - PCT - Retail pharmacy-Specialist47.50	5	✓ Methotrexate DBL
*	Inj 7.5 mg prefilled syringe14.61	1	Methotrexate Sandoz
*	Inj 10 mg prefilled syringe14.66	1	Methotrexate Sandoz
*	Inj 15 mg prefilled syringe14.77	1	Methotrexate Sandoz
*	Inj 20 mg prefilled syringe	1	Methotrexate Sandoz
*	Inj 25 mg prefilled syringe	1	Methotrexate Sandoz
*	Inj 30 mg prefilled syringe	1	Methotrexate Sandoz
*	Inj 25 mg per ml, 2 ml vial - PCT - Retail pharmacy-Specialist30.00	5	Methotrexate DBL Onco-Vial
*	Inj 25 mg per ml, 20 ml vial - PCT - Retail pharmacy-Specialist45.00	1	✓ DBL Methotrexate Onco-Vial
*	Inj 100 mg per ml, 10 ml - PCT - Retail pharmacy-Specialist25.00	1	✓ Methotrexate Ebewe
*	Inj 100 mg per ml, 50 ml vial – PCT – Retail		
	pharmacy-Specialist79.99	1	✓ Methotrexate Ebewe
*	Inj 1 mg for ECP - PCT only - Specialist	1 mg	✓ Baxter
*	Inj 5 mg intrathecal syringe for ECP - PCT only - Specialist4.73	5 mg OP	✓ Baxter
PΕ	METREXED - PCT only - Specialist - Special Authority see SA1679 on the	next page	
	Inj 100 mg vial60.89	1	✓ Juno Pemetrexed
	Inj 500 mg vial217.77	1	✓ Juno Pemetrexed
	Inj 1 mg for ECP	1 mg	✓ Baxter

	Subsidy		Fully	Brand or
(Mar	nufacturer's Price)	Subsic	lised	Generic
	\$	Per	•	Manutacturer

⇒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 Permetrexed 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

THIOGUANINE - PCT - Retail pharmacy-Specialist

- 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.

Tah 40 mg 126.31

Tub 40 mg		20	Lunvio	
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 pharr	nacy-Specialist			
Cap 0.5 mg	1,175.87	100	✓ Agrylin	
ARSENIC TRIOXIDE - PCT only - Specialist				
Inj 1 mg per ml, 10 ml vial	4,817.00	10	✓ Phenasen	
Ini 10 mg for FCP		10 ma OP	✓ Baxter	

25

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	Subsidy (Manufacturer's Price \$	e) Subs Per	Fully sidised	Brand or Generic Manufacturer
BLEOMYCIN SULPHATE - PCT only - Specialist Inj 15,000 iu, vial	185.16	1	✓ D	BL Bleomycin Sulfate
Inj 1,000 iu for ECP	14.32	1,000 iu	✓ B	axter
BORTEZOMIB – PCT only – Specialist – Special Authority see S Inj 2.5 mg vial		1	✓ B	ortezomib Juno S29 829
Inj 3.5 mg vial	105.00	1	✓ B	ortezomib Dr Reddy's S29 S29 ortezomib Dr-Reddy's ortezomib Juno S29
Inj 1 mg for ECP	31.20	1 mg	✓ B	axter
(Bortezomib Juno S29 S29 Inj 2.5 mg vial to be delisted 1 Augu (Bortezomib Dr Reddy's S29 S29 Inj 3.5 mg vial to be delisted 1	st 2022) August 2022)	J		

(Bortezomib Juno S29 Inj 3.5 mg vial to be delisted 1 August 2022)

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:

Fither:

- 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 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

	Subsidy		Fully Brand or
	(Manufacturer's Price) \$	Per	Subsidised Generic Manufacturer
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		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		1	✓ Epirubicin Ebewe
Inj 2 mg per ml, 100 ml vial		1	✓ Epirubicin Ebewe
Inj 1 mg for ECP		1 mg	✓ Baxter
ETOPOSIDE		Ū	
Cap 50 mg - PCT - Retail pharmacy-Specialist	340.73	20	✓ Vepesid
Cap 100 mg - PCT - Retail pharmacy-Specialist		10	✓ Vepesid
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specia		1	✓ Rex Medical
Inj 1 mg for ECP - PCT only - Specialist		1 mg	✓ Baxter
ETOPOSIDE PHOSPHATE - PCT only - Specialist			
Inj 100 mg (of etoposide base)	40.00	1	✓ Etopophos
Inj 1 mg (of etoposide base) for ECP		1 mg	✓ Baxter
HYDROXYUREA [HYDROXYCARBAMIDE] - PCT - Retail pha		ŭ	
Cap 500 mg	23.82	100	✓ Devatis
IDARUBICIN HYDROCHLORIDE		100	<u> </u>
Inj 5 mg vial - PCT only - Specialist	100 74	1	✓ Zavedos
Inj 10 mg vial – PCT only – Specialist		1	✓ Zavedos ✓ Zavedos
Inj 1 mg for ECP – PCT only – Specialist		1 mg	
, , ,		ı my	Daxlei
LENALIDOMIDE – Retail pharmacy-Specialist – Special Author 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

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

continued...

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:

- 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	✓ <u>Uromitexan</u>
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 S29
Inj 20 mg vial	3,275.00	1	✓ Omegapharm S29
, ,			✓ 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		1 mg	✓ Baxter
OLAPARIB - Retail pharmacy-Specialist - Special Authority see	e SA1883 below		
Tab 100 mg	3,701.00	56	✓ Lynparza
Tab 150 mg	3,701.00	56	✓ Lynparza

⇒SA1883 Special Authority for Subsidy

Initial application 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:

All of the following:

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

continued...

- 1 Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
- 2 There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
- 3 Patient has received at least two lines of previous treatment with platinum-based chemotherapy; and
- 4 Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line of platinum-based chemotherapy; and
- 5 Patient's disease must have achieved partial or complete response to treatment with the immediately preceding platinum-based regimen; and
- 6 Patient's disease has not progressed following prior treatment with olaparib; and
- 7 Treatment will be commenced within 8 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
- 8 Treatment to be administered as maintenance treatment; and
- 9 Treatment not to be administered in combination with other chemotherapy.

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 remains clinically appropriate and patient is benefitting from treatment; and
- 2 No evidence of progressive disease; and
- 3 Treatment to be administered as maintenance treatment; and
- 4 Treatment not to be administered in combination with other chemotherapy.

Note: *Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.

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 SA19	979 below		
Inj 750 iu per ml, 5 ml vial	3,455.00	1	✓ Oncaspar LYO S29

⇒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:

- 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	I) – PCT only – Specialist
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	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	I Generic
	\$	Per	•	Manufacturer
PROCARBAZINE HYDROCHLORIDE - PCT - Retail pharma	cy-Specialist			
Cap 50 mg	980.00	50	✓	Natulan S29
TEMOZOLOMIDE - Special Authority see SA1741 below - Re	etail pharmacy			
Cap 5 mg	9.13	5	1	Temaccord
Cap 20 mg	16.38	5	1	Temaccord
, •	18.30		✓	Apo-Temozolomide
	136.00	14	1	Accord S29
Cap 100 mg	35.98	5	1	Temaccord
•	40.20		1	Apo-Temozolomide
	532.00	14	1	Accord S29
Cap 140 mg	50.12	5	✓	Temaccord
	400.00		1	Amneal S29
Cap 180 mg	620.00	14	1	Accord S29
Cap 250 mg		5	1	Temaccord
•	688.00		1	Amneal S29

⇒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
- 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:

Fither:

- 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:

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Sub: Per	sidised ✓	Generic Manufacturer	

continued...

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	I 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
VENETOCLAX - Retail pharmacy-Specialist - Special Authority	see SA1868 belo)W	
Tab 14 × 10 mg, 7 × 50 mg, 21 × 100 mg	1,771.86	42 OP	✓ Venclexta
Tab 10 mg		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

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

continued...

recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

- 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-Specialist270.37	5	✓ Hospira
Inj 1 mg for ECP - PCT only - Specialist6.00	1 mg	✓ Baxter
VINCRISTINE SULPHATE		
Inj 1 mg per ml, 1 ml vial - PCT - Retail pharmacy-Specialist74.52	5	DBL Vincristine Sulfate
Inj 1 mg per ml, 2 ml vial - PCT - Retail pharmacy-Specialist102.73	5	DBL Vincristine Sulfate
Inj 1 mg for ECP - PCT only - Specialist12.60	1 mg	✓ Baxter
VINORELBINE - PCT only - Specialist		
Inj 10 mg per ml, 1 ml vial12.00	1	✓ Navelbine
42.00		✓ Vinorelbine Ebewe
Inj 10 mg per ml, 5 ml vial56.00	1	✓ Navelbine
210.00		✓ Vinorelbine Ebewe
328.65		✓ Sagent S29
Inj 1 mg for ECP1.25	1 mg	✓ Baxter
Inj 50 mg for ECP	50 mg OP	✓ Baxter (Sagent)

Protein-tyrosine Kinase Inhibitors

ALECTINIB – Retail pharmacy-Specialist – Special Authority see SA1870 below
Wastage claimable

⇒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

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

continued...

Al K 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

✓ Sprycel	60	Tab 20 mg3,774.06
✓ Sprycel	60	Tab 50 mg6,214.20
✓ Sprycel	60	Tab 70 mg

⇒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
 - 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/

ERLOTINIB - Retail pharmacy-Specialist - Special Authority se	ee SA2000 below		
Tab 100 mg	764.00	30	✓ Tarceva
Tab 150 mg	1,146.00	30	Tarceva

⇒SA2000 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:

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

continued...

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 Fither:
 - 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.

GEFITINIB - Retail pharmacy-Specialist - Special Authority see SA2001 below

⇒SA2001 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 Fither
 - 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.

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.

	below	2,400.00	60	✓ Glivec
*	Cap 100 mg		60	✓ Imatinib-Rex
	Cap 400 mg		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 <u>schedule.pharmac.govt.nz/SAForms</u>, 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:

Subsidy	,	Fully	Brand or	
(Manufacturer's Pri	ce)	Subsidised	Generic	
\$	Pe	er 🗸	Manufacturer	

continued...

- 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 \$A2035 below - Retail pharmacy

Note – no new patients to be initiated on lapatinib ditosylate.

⇒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 on the next page

Wastana	claimable
Wasiaye	Cialifiable

Tab 75 mg4,000.00	21	✓ Ibrance
Tab 100 mg4,000.00	21	✓ Ibrance
Tab 125 mg4,000.00	21	✓ Ibrance

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

⇒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

- 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 Authori	y see SA1190 below – F	Retail pharmacy
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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:

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

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 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 benefiting 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.

RUXOLITINIB - Special Authority see SA1890 below - Retail pharmacy

Wastage claimable

Tab 5 mg	2,500.00	56	Jakavi
Tab 10mg	·	56	Jakavi
Tab 15 mg	·	56	✓ Jakavi
Tab 20 mg	·	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.

	Subsidy (Manufacturer's Price)	Su Per	Fully bsidised	Brand or Generic Manufacturer	
SUNITINIB - Special Authority see SA2002 below - Reta	il nharmacy	rei		Manuacturer	_
Cap 12.5 mg		28	√ S	Sunitinib Pfizer	
3	2,315.38		√ S	Sutent	
Cap 25 mg	416.77	28	√ S	Sunitinib Pfizer	
	4,630.77		√ S	Sutent	
Cap 50 mg	694.62	28	√ S	Sunitinib Pfizer	
	9,261.54		√ S	Sutent	
(Sutent Cap 12.5 mg to be delisted 1 July 2022)					

(Sutent Cap 25 mg to be delisted 1 July 2022)

(Sutent Cap 50 mg to be delisted 1 July 2022)

⇒SA2002 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:
 - 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

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

continued...

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.

Endocrine Therapy

For GnRH ANALOGUES - refer to HORMONE PREPARATIONS, Trophic Hormones, page 83

ABIRATERONE ACETATE - Retail pharmacy-Specialist - Special Authority see SA2003 below

Wastage claimable

⇒SA2003 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

S29

	Subsidy (Manufacturer's Price)	Subs	Fully sidised	Brand or Generic	
	\$	Per	1	Manufacturer	
continued					
2. No evidence of clinical disease progression: 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.

BICALUTAMIDE			
Tab 50 mg	4.21	28	✓ Binarex
FLUTAMIDE			
Tab 250 mg	107.55	90	✓ Prostacur
•	119.50	100	Flutamin
FULVESTRANT - Retail pharmacy-Specialist - Special Authorit	ty see SA1895 be	low	
Inj 50 mg per ml, 5 ml prefilled syringe	1,068.00	2	✓ Faslodex

⇒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 S29
	63.53		✓ Apo-Megestrol

(Megace §29 Tab 160 mg to be delisted 1 February 2023) (Apo-Megestrol Tab 160 mg to be delisted 1 May 2022)

	Subsidy (Manufacturer's Price)	_	Fully Subsidised	Generic
	\$	Per		Manufacturer
OCTREOTIDE				
Inj 50 mcg per ml, 1 ml vial	30.64	5	•	Octreotide
				MaxRx S29
	56.87		✓	DBL Octreotide
Inj 100 mcg per ml, 1 ml vial	40.00	5	1	DBL Octreotide
Inj 500 mcg per ml, 1 ml vial	145.00	5	✓	DBL Octreotide
	222.00		✓	Octreotide
				(Sun) \$29
Inj 50 mcg per ml, 1 ml ampoule	27.58	5	1	Max Health
	30.64		1	Octreotide GH S29
Max Health to be Principal Supply on 1 June 2022				
Inj 100 mcg per ml, 1 ml ampoule	32.71	5	1	Max Health
			1	Octreotide GH S29
Max Health to be Principal Supply on 1 June 2022				
Inj 500 mcg per ml, 1 ml ampoule	113.10	5	1	Max Health
			1	Octreotide GH S29
Max Health to be Principal Supply on 1 June 2022				
Octreotide MaxRx \$29 Inj 50 mcg per ml, 1 ml vial to be delisted	l 1 June 2022)			
DBL Octreotide Inj 50 mcg per ml, 1 ml vial to be delisted 1 June				
DBL Octreotide Inj 100 mcg per ml, 1 ml vial to be delisted 1 June	,			
DBL Octreotide Inj 500 mcg per ml, 1 ml vial to be delisted 1 June	e 2022)			
Octreotide (Sun) S29 Inj 500 mcg per ml, 1 ml vial to be delisted				
Octreotide GH S29 Inj 50 mcg per ml, 1 ml ampoule to be deliste	,			
Octreotide GH S29 Inj 100 mcg per ml, 1 ml ampoule to be delis	,			
Octreotide GH (\$29) Inj 500 mcg per ml, 1 ml ampoule to be delis				
OCTREOTIDE LONG-ACTING – Special Authority see SA2072 b		acy	,	Outro attala Daniel
Inj depot 10 mg prefilled syringe	439.97	1	•	Octreotide Depot
1.1.1.00	0.47.00			Teva
Inj depot 20 mg prefilled syringe	647.03	1	•	Octreotide Depot

⇒SA2072 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.

Inj depot 30 mg prefilled syringe.......718.55

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:

Both:

1 The patient has acromegaly; and

continued...

Teva

✓ Octreotide Depot Teva

1

Subsidy (Manufacturer's Price)	Ful Subsidise	d Generic	
•	Per •	Manufacturer	

continued...

- 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

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 Fither:
 - 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
- 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 mg15.00	60	✓ <u>Tamoxifen Sandoz</u>
*	Tab 20 mg	60	✓ Tamoxifen Sandoz

Aromatase Inhibitors

AN	40	rn/	77	\sim 1	_
AIN	A.	ıπι	<i>)/</i> (л	г

MIN/	43 I HOZOLE			
*	Tab 1 mg	4.55	30	✓ Anatrole

	Subsidy (Manufacturer's Price) \$		Fully Subsidised	Brand or Generic Manufacturer
EXEMESTANE * Tab 25 mg	14.50	30	√ P	fizer Exemestane
LETROZOLE * Tab 2.5 mg	5.84	30	✓ <u>L</u>	<u>etrole</u>

Immunosuppressants

Cytotoxic Immunosuppressants

AZATHIOPRINE			
* Tab 25 mg	7.35	60	Azamun
* Tab 50 mg	7.60	100	✓ Azamun
* Inj 50 mg vial		1	✓ Imuran
MYCOPHENOLATE MOFETIL			
Tab 500 mg	35.90	50	Cellcept
Cap 250 mg	35.90	100	✓ Cellcept
Powder for oral lig 1 g per 5 ml - Subsidy by endorsement	187 25	165 ml OP	✓ Cellcent

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 - Re	etail pharmacy		
Inj 25 mg	690.00	4	Enbrel
Inj 25 mg autoinjector	690.00	4	✓ Enbrel
Inj 50 mg autoinjector	1,050.00	4	✓ Enbrel
Inj 50 mg prefilled syringe		4	✓ Enbrel

⇒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:

Fither:

- 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 DHB hospital in accordance with the HML rules; and
 - 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:

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

continued...

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:

Fither:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and
 - 1.2 Fither:
 - 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 Fither:
 - 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

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

Subsidy		Fully	Brand or
(Manufacturer's Price)	9	Subsidised	Generic
\$	Per	✓	Manufacturer

continued...

- 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;
- 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.

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: Fither:

- 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 Fither:
 - 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:

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- 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 Fither:
 - 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:
 - 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.

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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 pvoderma 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 — (pvoderma 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
 - - 1.2.1 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:
 - 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 hydroxychloroguine sulphate (at maximum tolerated doses unless contraindicated); and
 - 2.5 Fither:
 - 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

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- 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 Fither:
 - 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 Fither:
 - 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
 - 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:

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All of the following:

- 1 Fither:
 - 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 Fither:
 - 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 2.1.2 Fither:
 - 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 plague 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:
 - 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 Fither

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- 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 - Specia	alist		
Inj 50 mg per ml, 5 ml	2,774.48	5	✓ ATGAM
BACILLUS CALMETTE-GUERIN (BCG) VACCINE - PCT only	Specialist		
Subsidised only for bladder cancer.			
Inj 2-8 × 100 million CFU	149.37	1	✓ OncoTICE
Inj 40 mg per ml, vial	176.90	3	✓ SII-Onco-BCG S29

Monoclonal Antibodies

oelow – Retail pharm	acy	
190.00	1	Amgevita
375.00	2	✓ Amgevita
375.00	2	✓ Amgevita
	190.00 375.00	375.00 2

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Initial application — (Behcet's disease - severe) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and
- 2 Fither:
 - 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 The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not 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:

All of the following:

- 1 Patient has hidradenitis suppurativa Hurley Stage III or Hurley Stage III lesions in distinct anatomic areas; and
- 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
- 3 Patient has 3 or more active lesions: and
- 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:

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- 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 Both:
 - 1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plague psoriasis; and
 - 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects; or
 - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept 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 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 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 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:

Fither:

- 1 Both:
 - 1.1 Patient had "whole body" severe chronic plague psoriasis at the start of treatment; and
 - 1.2 Fither:
 - 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:

Both:

- 1 Patient has pyoderma gangrenosum*; and
- 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.

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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:

All of the following:

- 1 Patient has severe active Crohn's disease; and
- 2 Any of the following:
 - 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 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 therapy with immunomodulators and corticosteroids; and
- 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:

All of the following:

- 1 Paediatric patient has active Crohn's disease; and
- 2 Either:
 - 2.1 Patient has a PCDAI score of greater than or equal to 30; or
 - 2.2 Patient has extensive small intestine disease; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
- 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:

All of the following:

- 1 Patient has confirmed Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
 - 2.2 Patient has one or more rectovaginal fistula(e); or
 - 2.3 Patient has complex peri-anal fistula; and
- 3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

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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 had an initial Special Authority approval for infliximab 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 — (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</p>
- 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 Patient has had an initial Special Authority approval for infliximab 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 — (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

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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:

Fither:

- 1 Both:
 - 1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; 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 ankylosing spondylitis; or
- 2 All of the following:
 - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis 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 sacroillitis demonstrated by radiology imaging; and
 - 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
 - 2.5 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 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; 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 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:

Fither:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and
- 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects; or
 - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria 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 Either:
 - 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).

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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:

Fither:

1 Both:

- 1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
- 1.2 Fither:
 - 1.2.1 Patient has experienced intolerable side effects: or
 - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria 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 — (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 Both:

- 1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic 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 from to meet the renewal criteria for psoriatic arthritis; or

2 All of the following:

- 2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
- 2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
- 2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and

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- 2.4 Either:
 - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen 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 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; 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 — (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 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept 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 from etanercept to meet the renewal criteria for rheumatoid arthritis: or
- 2 All of the following:
 - 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 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
 - 25 Fither
 - 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:

Fither:

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- 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.

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 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and
 - 12 Fither
 - 1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
 - 1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
- 2 All of the following:
 - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; 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, NSAIDs and methotrexate; and
 - 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:

All of the following:

1 Patient has
2 Either:

- 1 Patient has histologically confirmed ulcerative colitis; and
 - 2.1 Patient's SCCAI score is greater than or equal to 4; or
 - 2.2 Patient's 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 therapy with immunomodulators and systemic corticosteroids; and
- 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:

Fither:

- 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:

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 each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and
- 3 Any of the following:
 - 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
 - 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
 - 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

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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:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has axial inflammatory pain for six months or more; and
- 3 Patient is unable to take NSAIDs; and
- 4 Patient has bilateral sacroiliitis demonstrated by radiological imaging; and
- 5 Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
- 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:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
- 3 Patient has tried and not responded to at least three months of methotrexate, or azathioprine at a maximum tolerated dose; and
- 4 Patient has tried and not responded to at least three months of sulfasalazine at a maximum tolerated dose; and
- 5 Any of the following:
 - 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
 - 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
 - 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:

- 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 on the next page - Retail pharmacy

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	· ·	2	Humira

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

⇒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:

Roth:

- 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</p>
 - 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:

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 Fither:
 - 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

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(Manufacturer's Price)		Subsidised	Generic	
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- 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 Fither:
 - 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;
 - 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 Fither:
 - 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:

- 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 Fither:

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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- 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 Fither:
 - 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:

All of the following:

- 1 Fither:
 - 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

Subsidy	Fully	Brand or	
(Manufacturer's Price)	Subsidised	Generic	
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- 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 Fither:
 - 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plague 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 valuee; 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
- 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

Subsidy		Fully	Brand or
(Manufacturer's Price)		Subsidised	Generic
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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</p>

✓ Eylea

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

⇒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 Fither:
 - 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.

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

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

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- 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.

CASIRIVIMAB AND IMDEVIMAB - [Xpharm] - Special Authority see SA2096 below

⇒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.

INFLIXIMAB - PCT only - Special Authority see \$A2082 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

Subsidy		Fully	Brand or	
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\$	Per	✓	Manufacturer	

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- 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection;
- 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 Fither
 - 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
- 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:

Subsidy		Fully	Brand or
(Manufacturer's Price)	9	Subsidised	Generic
\$	Per	✓	Manufacturer

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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
 - 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</p>
- 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.

Subsidy		Fully	Brand or
(Manufacturer's Price)	S	ubsidised	Generic
` \$	Per	1	Manufacturer

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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 Fither
 - 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 Fither:
 - 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 neurosarcoiosis by a multidisciplinary team; and
- 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:

Fither:

- 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 symptomology.

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:

Fither:

- 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 Fither:

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- 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:

Roth:

- 1 Fither:
 - 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 Fither:
 - 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

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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- 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 Plague psoriasis; or
- 2.12 Neurosarcoidosis; 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:
 - 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 Fither:

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- 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
- 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

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- 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</p>
- 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 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 Fither:
 - 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

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- 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 SA1896 below	 Retail pharmacy 		
Inj 100 mg prefilled pen	1,638.00	1	Nucala
Inj 100 mg vial	1,638.00	1	✓ Nucala

⇒SA1896 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
- 6 Either:
 - 6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
 - 6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months: and
- 7 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment.

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 Fither:
 - 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 A	uthority see SA1627 on the	next page	
Inj 25 mg per ml, 40 ml vial	5,910.00	1	Gazyva
Inj 1 mg for ECP	6.21	1 mg	✓ Baxter

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⇒SA1627 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</p>
- 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 1.5×10^9 /L and platelets greater than or equal to 75×10^9 /L.

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 Fither:
 - 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 Fither:
 - 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.

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:

- 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 Patient is chemotherapy treatment naïve; or
 - 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 The patient has good performance status (ECOG grade 0-1); and
- 4 Pertuzumab to be administered in combination with trastuzumab; and
- 5 Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
- 6 Pertuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology);
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab.

RITUXIMAB (MABTHERA) – PCT only – Specialist – S	pecial Authority see SA197	6 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:

- 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 Fither:
 - 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 Fither:
 - 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

Subsidy		Fully	Brand or
(Manufacturer's Price)	Subsidised		Generic
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- 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 Fither:
 - 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:
 - 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 SA2083 on the next page

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)

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⇒SA2083 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
 - 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:

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- 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:

Roth:

1 Either:

- 1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or
- 1.2 All of the following:
 - 1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL;
 - 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 patients 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

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- 2 The patients has responded to the most recent course of rituximab; and
- 3 The patient has not received rituximab in the previous 6 months.

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.

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

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- 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.

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*; and
- 2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with * 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.

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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:

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.

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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
- 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:

Fither:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
- 2 All of the following:
 - 2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and
 - 2.2 An initial response lasting at least 12 months was demonstrated; and

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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
- 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.

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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
- 3 Fither
 - 3.1 Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be 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 x 1,000mg 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 be effective at controlling active disease; 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

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 Fither:
 - 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

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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 — (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/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 — (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 Fither:
 - 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/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:

Fither:

- 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

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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 Fither:
 - 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:
 - 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 — (desensisation 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 allogenic 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.

SECUKINUMAB - Special Authority see SA2084 on the	next page – Retail pharmac	у	
Inj 150 mg per ml, 1 ml prefilled syringe	799.50	1	✓ Cosentyx
	1,599.00	2	✓ Cosentyx

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

⇒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 DHB hospital in accordance with the General Rules of the Pharmaceutical Schedule, for severe chronic plague psoriasis; and
- 2 Fither
 - 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 Fither:
 - 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
 - 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:

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Fither:
 - 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:

Fither:

- 1 Both:
 - 1.1 Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis; and
 - 1.2 Fither:
 - 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;
 - 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:

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

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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

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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.

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TOCILIZUMAB - PCT only - Special Authority see SA2100 below

inj 20 mg per mi, 4 mi viai220.00	1	Actemra
		✓ Actemra S29 S29
		✓ RoActemra S29 S29
880.00	4	✓ RoActemra S29 S29
Inj 20 mg per ml, 10 ml vial550.00	1	✓ Actemra
		✓ Actemra S29 S29
		✓ RoActemra S29 S29
Inj 20 mg per ml, 20 ml vial1,100.00	1	✓ Actemra
		✓ Actemra S29 S29
		✓ RoActemra S29 S29
4,400.00	4	✓ RoActemra S29 S29
Inj 1 mg for ECP2.85	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:

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:

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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 Fither:
 - 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 DHB hospital in accordance with the Section H rules: and
 - 3.2.2 Fither:
 - 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
 - 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;
 - 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 Fither:

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- 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:

Fither:

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 DHB hospital in accordance with the General Rules of the Pharmaceutical Schedule; 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
- 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.

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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 barcitinib.

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
- 2 Fither:
 - 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 on the next page

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

bsidy urer's Price) Subs	Fully	Brand or Generic
 \$ Per	•	Manufacturer

⇒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 Fither:
 - 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
- 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);
- 2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and

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

continued...

- 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 Fither:
 - 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 SA1871 below

Inj 100 mg vial	2,320.00	1	Kadcyla
Inj 160 mg vial	3,712.00	1	✓ Kadcyla
Inj 1 mg for ECP	24.52	1 mg	✓ Baxter

⇒SA1871 Special Authority for Subsidy

Initial application 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 Treatment to be discontinued at disease progression.

Renewal 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.

	Subsidy	0.1	Fully	Brand or
(Ma	inufacturer's Price)	Subsi	dised	Generic
	\$	Per	•	Manufacturer

Programmed Cell Death-1 (PD-1) Inhibitors

		Special Authority see SA2006 below	NIVOLUMAB - PCT only - Specialist - S
Opdivo	1	1,051.98	Inj 10 mg per ml, 4 ml vial
✓ Opdivo	1	2,629.96	Inj 10 mg per ml, 10 ml vial
✓ Baxter	1 ma	27.62	Ini 1 mg for FCP

⇒SA2006 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:

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

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

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	facturer's Price)	Subsidised	Generic
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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 A	Authority see SA2007 below	
Inj 25 mg per ml, 4 ml vial	4,680.00 1	✓ Keytruda
Inj 1 mg for ECP	49.14 1 mg	✓ Baxter

⇒SA2007 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
 - 1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
 - 1.2 Fither:
 - 1.2.1 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; or
 - 1.2.2 Both:
 - 1.2.2.1 Patient has measurable disease as defined by RECIST version 1.1; and
 - 1.2.2.2 Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and

Subsidy (Manufacturer's Price)	Sı	Fully ubsidised	Brand or Generic
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- 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 ph Wastage claimable	armacy		
Tab 10 mg	6.512.29	30	✓ Afinitor
Tab 5 mg		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: 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.

	Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic
	\$	Per	•	Manufacturer
SIROLIMUS - Special Authority see SA2005 below - Retail pha	rmacy			
Tab 1 mg	749.99	100	✓	Rapamune
Tab 2 mg	1,499.99	100	✓	Rapamune
Oral liq 1 mg per ml	449.99	0 ml 0	OP 🗸 I	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
- · Leukoencepthalopathy; 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:

- 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

Subsidy		Fully	Brand or
(Manufacturer's Price)	Sı	ubsidised	Generic
\$	Per	1	Manufacturer

continued...

- 2 Demonstrated stabilisation or improvement in renal function; and
- 3 The patient has not experienced angiomyolipoma haemorrhage or significant adverse effects to sirolimus treatment; and
- 4 The treatment remains appropriate and the patient is benefitting from treatment.

Note: Indications marked with * are unapproved indications

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	•	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 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

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

⇒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 DHB hospital in accordance with the Section H rules; 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:

Fither:

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

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

⇒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 SA	1367 above – I	Retail pharma	су
Initiation kit - 5 vials freeze dried venom with diluent	305.00	1 OP	✓ VENOX S29
Maintenance kit - 1 vial freeze dried venom with diluent	305.00	1 OP	✓ VENOX S29
Maintenance kit - 6 vials 120 mcg freeze dried venom, with			
diluent	285.00	1 OP	✓ Venomil S29
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 S29
WASP VENOM ALLERGY TREATMENT - Special Authority see S	SA1367 above	– Retail pharr	macy
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 S29
Treatment kit (Paper wasp venom) - 6 vials 120 mcg freeze			
dried venom, with diluent	305.00	1 OP	✓ Venomil S29
Treatment kit (Yellow Jacket venom) - 1 vial 550 mcg freeze			
dried venom, with diluent	305.00	1 OP	✓ Hymenoptera S29
Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze	205.00	1 OD	√ Albay
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	205.00	1 OP	✓ Venomil \$29
uneu venom, wim unuerit	303.00	I OF	A ACHOUNII 258

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	\$	Per	✓ Manufacturer
Autibistanduss			
Antihistamines			
CETIRIZINE HYDROCHLORIDE			
* Tab 10 mg	1 12	100	✓ Zista
* Oral liq 1 mg per ml	2 84	200 ml	✓ Histaclear
CHLORPHENIRAMINE MALEATE		200	<u></u>
* Oral liq 2 mg per 5 ml	0.27	500 ml	✓ Histafen
	9.37	500 1111	• пізіаісіі
DEXTROCHLORPHENIRAMINE MALEATE			
* Tab 2 mg	4- 4-4	40	
	(8.40)		Polaramine
	1.01	20	
	(5.99)		Polaramine
* Oral liq 2 mg per 5 ml		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	1.69	100	✓ Lorafix
* Oral liq 1 mg per ml		100 ml	✓ Haylor syrup
PROMETHAZINE HYDROCHLORIDE			
* Tab 10 mg	2.02	50	✓ Allersoothe
* Tab 25 mg		50	✓ Allersoothe
* Oral liq 1 mg per 1 ml		100 ml	✓ Allersoothe
* Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a		5	✓ Hospira
.,			
Inhaled Corticosteroids			
BECLOMETHASONE DIPROPIONATE			_
Aerosol inhaler, 50 mcg per dose		00 dose OP	✓ Qvar
Aerosol inhaler, 50 mcg per dose CFC-free		00 dose OP	✓ Beclazone 50
Aerosol inhaler, 100 mcg per dose		00 dose OP	✓ Qvar
Aerosol inhaler, 100 mcg per dose CFC-free		00 dose OP	✓ Beclazone 100
Aerosol inhaler, 250 mcg per dose CFC-free	22.67 2	00 dose OP	✓ Beclazone 250
BUDESONIDE			
Powder for inhalation, 100 mcg per dose	17.00 2	00 dose OP	✓ Pulmicort
			Turbuhaler
Powder for inhalation, 200 mcg per dose	19.00 2	00 dose OP	✓ Pulmicort
			Turbuhaler
Powder for inhalation, 400 mcg per dose	32.00 2	00 dose OP	✓ Pulmicort
•			Turbuhaler

	Subsidy		Fully Brand or
	(Manufacturer's	Price) Subsi	dised Generic
	\$	Per	✓ Manufacturer
UTICASONE			
Aerosol inhaler, 50 mcg per dose	7.19	120 dose OP	✓ Flixotide
Powder for inhalation, 50 mcg per dose		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		120 dose OP	✓ Flixotide
Aerosol inhaler, 250 mcg per dose		120 dose OP	✓ Flixotide
Powder for inhalation, 250 mcg per dose		60 dose OP	✓ Flixotide Accuhaler
nhaled Long-acting Beta-adrenoceptor Agoni	ists		
ORMOTEROL FUMARATE			
ORMOTEROL FUMARATE		CO d	
Powder for inhalation, 12 mcg per dose, and monodose de		60 dose	Fave dil
	(35.80)		Foradil
ORMOTEROL FUMARATE DIHYDRATE			
Powder for inhalation 4.5 mcg per dose, breath activated			
(equivalent to eformoterol fumarate 6 mcg metered do	se)10.32	60 dose OP	
	(16.90)		Oxis Turbuhaler
DACATEROL			
Powder for inhalation 150 mcg	61.00	30 dose OP	✓ Onbrez Breezhaler
Powder for inhalation 300 mcg		30 dose OP	✓ Onbrez Breezhaler
LMETEROL			
Aerosol inhaler CFC-free, 25 mcg per dose	25.00	120 dose OP	✓ Serevent
Powder for inhalation, 50 mcg per dose, breath activated		60 dose OP	✓ Serevent Accuhaler
rowder for initialation, 50 mbg per dose, breath activated	25.00	00 dose or	Selevelii Acculialei
nhaled Corticosteroids with Long-Acting Beta	a-Adrenocept	or Agonists	
nhaled Corticosteroids with Long-Acting Beta	a-Adrenocept	or Agonists	
	a-Adrenocept	or Agonists	
DESONIDE WITH EFORMOTEROL		or Agonists	
IDESONIDE WITH EFORMOTEROL Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide	e with	tor Agonists 120 dose OP	✓ DuoResp Spiromax
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with41.50	-	✓ DuoResp Spiromax
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with41.50 narate	-	✓ DuoResp Spiromax
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with41.50 narate nog	-	✓ DuoResp Spiromax
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with 41.50 narate ncg 2	-	
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP	✓ DuoResp Spiromax
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP	✓ DuoResp Spiromax✓ Vannair
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP	✓ DuoResp Spiromax
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP 120 dose OP	✓ DuoResp Spiromax ✓ Vannair ✓ Symbicort Turbuhaler 100/6
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP	 ✓ DuoResp Spiromax ✓ Vannair ✓ Symbicort Turbuhaler 100/6 ✓ Vannair
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP 120 dose OP	✓ DuoResp Spiromax ✓ Vannair ✓ Symbicort Turbuhaler 100/6 ✓ Vannair ✓ Symbicort
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP	 ✓ DuoResp Spiromax ✓ Vannair ✓ Symbicort Turbuhaler 100/6 ✓ Vannair
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP	 ✓ DuoResp Spiromax ✓ Vannair ✓ Symbicort Turbuhaler 100/6 ✓ Vannair ✓ Symbicort Turbuhaler 200/6
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP	 ✓ DuoResp Spiromax ✓ Vannair ✓ Symbicort Turbuhaler 100/6 ✓ Vannair ✓ Symbicort Turbuhaler 200/6 ✓ Symbicort
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP	 ✓ DuoResp Spiromax ✓ Vannair ✓ Symbicort Turbuhaler 100/6 ✓ Vannair ✓ Symbicort Turbuhaler 200/6 ✓ Symbicort
Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide 6 mcg eformoterol fumarate metered dose)	e with	120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP 120 dose OP	 ✓ DuoResp Spiromax ✓ Vannair ✓ Symbicort Turbuhaler 100/6 ✓ Vannair ✓ Symbicort Turbuhaler 200/6

20

✓ Duolin

	RESPIRATORY SYSTEM AND ALLERGI			:5
	Subsidy (Manufacturer's \$	Price) Subsi	Fully Brand or idised Generic Manufacturer	
LUTICASONE WITH SALMETEROL				
Aerosol inhaler 50 mcg with salmeterol 25 mcg		120 dose OP	✓ <u>Seretide</u>	
Aerosol inhaler 125 mcg with salmeterol 25 mcg		120 dose OP	✓ Seretide	
Powder for inhalation 100 mcg with salmeterol 50 mcg – No more than 2 dose per day		60 dose OP	✓ Seretide Accuhale	
Powder for inhalation 250 mcg with salmeterol 50 mcg – No		00 dose OF	• Seretide Accumate	71
more than 2 dose per day		60 dose OP	✓ Seretide Accuhale	r
Beta-Adrenoceptor Agonists				
SALBUTAMOL				
Oral liq 400 mcg per ml		150 ml	✓ <u>Ventolin</u>	
Infusion 1 mg per ml, 5 ml		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				
ALBUTAMOL				
Aerosol inhaler, 100 mcg per dose CFC free - Up to 1000				
dose available on a PSO	3.80	200 dose OP	Respigen	
	(0.00)		✓ SalAir	
Nobulinar calo 1 mg par ml 0 5 ml ampaula . Un to 20 nab	(6.00)		Ventolin	
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO		20	✓ Asthalin	
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb		20	- <u>Addiumi</u>	
available on a PSO		20	✓ Asthalin	
ERBUTALINE SULPHATE				
Powder for inhalation, 200 mcg per dose (equivalent to				
250 mcg metered dose), breath activated	22.20	120 dose OP	Bricanyl Turbuhal	er
Anticholinergic Agents				
PRATROPIUM BROMIDE				
Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dos	e			
available on a PSO		200 dose OP	✓ Atrovent	
Nebuliser soln, 250 mcg per ml, 2 ml ampoule - Up to 40 ne	eb			
available on a PSO	11.73	20	✓ <u>Univent</u>	
Inhaled Beta-Adrenoceptor Agonists with Antic	holinergic /	Agents		
SALBUTAMOL WITH IPRATROPIUM BROMIDE				
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg p	per			
dose CFC-free		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

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

Long-Acting Muscarinic Antagonists

GLYCOPYRRONIUM - Subsidy by endorsement

- a) Inhaled glycopyrronium treatment will not be subsidised if patient is also receiving treatment with subsidised tiotropium or umeclidinium.
- b) 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.

TIOTROPIUM BROMIDE - Subsidy by endorsement

- a) Tiotropium treatment will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or umeclidinium.
- b) 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.

UMECLIDINIUM - Subsidy by endorsement

- a) Umeclidinium will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or tiotropium bromide.
- b) 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.

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:

- 1 Patient has been stabilised on a long acting muscarinic antagonist; and
- 2 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:

- 1 Patient is compliant with the medication; and
- 2 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 mcg81.00 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 mcg81.00 60 dose OP ✓ Spiolto Respimat

UMECLIDINIUM WITH VILANTEROL - Special Authority see SA1584 above - Retail pharmacy

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	Brand or Generic	
\$	Per	✓	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

Troto: I monidono lo not cabolaleca in combination with cabol	alood milloddino.		
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	
Leukotriene Receptor Antagonists				
MONTELUKAST * Tab 4 mg	4.25	28	/	Montelukast Mylan
* Tab 5 mg * Tab 10 mg	4.25	28 28	1	Montelukast Mylan Montelukast Mylan
Methylxanthines AMINOPHYLLINE				-
* Inj 25 mg per ml, 10 ml ampoule – Up to 5 inj available on a PSO	180.00	5	•	DBL Aminophylline
THEOPHYLLINE * Tab long-acting 250 mg * Oral liq 80 mg per 15 ml		100 500 m		Nuelin-SR Nuelin
Mucolytics				
DORNASE ALFA – Special Authority see SA1978 below – Retail Nebuliser soln, 2.5 mg per 2.5 ml ampoule		6	1	Pulmozyme

⇒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 Autho	rity 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:
 - 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

RE	SPIRAT	ORY SYSTE	M AI	ND ALLERGIES
(Mar	Subsidy nufacturer's P \$		Fully dised	Brand or Generic Manufacturer
continued 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/ sweat collection system; and 4 Treatment with ivacaftor must be given concomitantly with stan 5 Patient must not have an acute upper or lower respiratory infection (including antibiotics) for pulmonary disease in the last 4 weeks 6 The dose of ivacaftor will not exceed one tablet or one sachet to applicant has experience and expertise in the management of SODIUM CHLORIDE Not funded for use as a nasal drop.	dard therap tion, pulmon prior to con wice daily; a	y for this condit nary exacerbation mmencing treation	ion; an	d changes in therapy
Soln 7%	24.50	90 ml OP	✓ <u>B</u>	iomed
Nasal Preparations				
Allergy Prophylactics				
BUDESONIDE Metered aqueous nasal spray, 50 mcg per dose Metered aqueous nasal spray, 100 mcg per dose FLUTICASONE PROPIONATE	2.84	200 dose OP 200 dose OP	√ <u>S</u>	teroClear teroClear
Metered aqueous nasal spray, 50 mcg per dose	1.98	120 dose OP	√ <u>F</u>	lixonase Hayfever & Allergy
IPRATROPIUM BROMIDE Aqueous nasal spray, 0.03%	5.23	15 ml OP	✓ <u>U</u>	nivent
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
a) Up to 25 dev available on a PSO b) Only on a PSO Low range	0.54	1	√ N	lini-Wright AFS
Normal range		1		Low Range lini-Wright Standard

✓ e-chamber Turbo

✓ e-chamber La

Grande

✓ Volumatic

1

1

220 ml (single patient)2.95

SPACER DEVICE

b) Only on a PSO

a) Up to 50 dev available on a PSO

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

Respiratory Stimulants

CAFFEINE CITRATE

Oral liq 20 mg per ml (10 mg base per ml)......15.10 25 ml OP ✓ <u>Biomed</u>

	Subsidy (Manufacturer's P \$	rice) S Per	Fully Subsidised	
Ear Preparations				
FLUMETASONE PIVALATE				
Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml O	P 🗸	Locacorten-Viaform ED's
			✓	Locorten-Vioform
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMY	CIN AND NYSTAT	IN		
Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate	9			
2.5 mg and gramicidin 250 mcg per g	5.16	7.5 ml O	P 🗸	Kenacomb
Ear/Eye Preparations				
DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN				
Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and				
gramicidin 50 mcg per ml		8 ml OF)	
gramician 30 mag per mi	(9.27)	0 1111 01		Sofradex
FRAMYCETIN SULPHATE	()			
Ear/Eye drops 0.5%	4.13	8 ml OF		
,	(8.65)			Soframycin
Eye Preparations				
Eye preparations are only funded for use in the eye, unless exp	licitly stated other	wise.		
Anti-Infective Preparations				
ACICLOVIR				
* Eye oint 3%	14.88	4.5 g Ol	•	ViruPOS
CHLORAMPHENICOL				
Eye oint 1%	1.55	5 g OP	1	Devatis
Eye drops 0.5%	1.54	10 ml O	P 🗸	Chlorafast
Funded for use in the ear*. Indications marked with *	are unapproved inc	dications.		
CIPROFLOXACIN				
Eye drops 0.3% - Subsidy by endorsement		5 ml OF		Ciprofloxacin Teva
When prescribed for the treatment of bacterial keratitis				
for the second line treatment of chronic suppurative of	, ,	r; and the p	prescription	on is endorsed accordingly.
Note: Indication marked with a * is an unapproved ind	ication.			
GENTAMICIN SULPHATE	44.40	F OF		O-mantia
Eye drops 0.3%	11.40	5 ml OF	•	Genoptic

235

Brolene

✓ Fucithalmic

✓ Tobrex

✓ Tobrex

10 ml OP

5 g OP

3.5 g OP

5 ml OP

(14.55)

* Eye drops 0.1%......2.97

PROPAMIDINE ISETHIONATE

TOBRAMYCIN

SODIUM FUSIDATE [FUSIDIC ACID]



Subsidy		Fully	Brand or
(Manufacturer's Price)	5	Subsidised	Generic
\$	Per	✓	Manufacturer

Corticosteroids and Other Anti-Inflammatory Preparations

 XAMETHASONE	E 06	3.5 g OP	✓ Maxidex
Eye oint 0.1%		5.5 g OP 5 ml OP	✓ Maxidex
Ocular implant 700 mcg - Special Authority see SA1680 below			
- Retail pharmacy1	,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 Fither
 - 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			
* Eve drops 0.1%	3.09	5 ml OP	✓ FML
•	5.20		✓ Flucon

	Subsidy		Fully	Brand or
	(Manufacturer's F	Price) Sub	sidised	Generic
	\$	Per	1	Manufacturer
EVOCABASTINE				
Eye drops 0.5 mg per ml	8.71	4 ml OP		
, , ,	(10.34)		L	ivostin
LODOXAMIDE				
Eye drops 0.1%	8.71	10 ml OP	✓ L	omide .
PREDNISOLONE ACETATE				
Eve drops 1%	5.93	10 ml OP	✓ P	rednisolone-AFT
7	7.00	5 ml OP	✓ P	red Forte
PREDNISOLONE SODIUM PHOSPHATE - Special Autho	rity see SA1715 belov	v – Retail phar	macy	
Eye drops 0.5%, single dose (preservative free)		20 dose	•	linims 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.

E ml OD

/ Davagram

Eva dra	ps 2%	
Eve ard	DS 2%	

SODIUM CROMOGLICATE

Eye drops 2%	1.79	5 ml OP	✓ <u>Rexacrom</u>
Glaucoma Preparations - Beta Blockers			
BETAXOLOL * Eye drops 0.25% * Eye drops 0.5% TIMOLOL		5 ml OP 5 ml OP	✓ Betoptic S✓ Betoptic
* Eye drops 0.25%* Eye drops 0.5%* Eye drops 0.5%, gel forming	2.04	5 ml OP 5 ml OP 2.5 ml OP	✓ <u>Arrow-Timolol</u> ✓ <u>Arrow-Timolol</u> ✓ Timoptol XE
Glaucoma Preparations - Carbonic Anhydrase	Inhibitors		
ACETAZOLAMIDE * Tab 250 mg BRINZOLAMIDE	17.03	100	✓ Diamox
* Eye drops 1%	7.30	5 ml OP	✓ <u>Azopt</u>
DORZOLAMIDE HYDROCHLORIDE * Eye drops 2%	9.77 (17.44)	5 ml OP	Trusopt
DORZOLAMIDE WITH TIMOLOL * Eye drops 2% with timolol 0.5%	2.73	5 ml OP	✓ <u>Dortimopt</u>
Glaucoma Preparations - Prostaglandin Analo	gues		
BIMATOPROST * Eye drops 0.03%	5.95	3 ml OP	✓ Bimatoprost Multichem

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

Bimatoprost Multichem to be Principal Supply on 1 April 2022

	Subsidy (Manufacturer's Pr	ice) Subs	Fully sidised	Brand or Generic Manufacturer
LATANOPROST	Ψ	101		Warrandotarer
* Eye drops 0.005%	1.82	2.5 ml OP	✓ To	<u>eva</u>
TRAVOPROST				
* Eye drops 0.004%	9.75	2.5 ml OP	✓ TI	<u>ravatan</u>
Glaucoma Preparations - Other				
BRIMONIDINE TARTRATE				
* Eye drops 0.2%	4.29	5 ml OP	✓ A	rrow-Brimonidine
BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE				
* Eye drops 0.2% with timolol maleate 0.5%	18.50	5 ml OP	√ C	ombigan
LATANOPROST WITH TIMOLOL				
Eye drops 0.005% with timolol 0.5%	2.49	2.5 ml OP	✓ A	rrow - Lattim
PILOCARPINE HYDROCHLORIDE				
* Eye drops 1%	4.26	15 ml OP	✓ Is	opto Carpine
* Eye drops 2%		15 ml OP		opto Carpine
* Eye drops 4% Subsidised for oral use pursuant to the Standard Form		15 ml OP	√ Is	opto Carpine
* Eye drops 2% single dose - Special Authority see SA0895	5			
below – Retail pharmacy	31.95	20 dose	✓ M	inims 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.

Mydriatics and Cycloplegics

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.

ATROPINE SULPHATE * Eye drops 1%	17.36	15 ml OP	✓ Atropt
CYCLOPENTOLATE HYDROCHLORIDE * Eye drops 1%	8.76	15 ml OP	✓ Cyclogyl
Eye drops 1%, single dose (preservative free) - Only on a prescription		20 dose	✓ Minims
(Minims Cyclopentolate Eye drops 1%, single dose (preservative			Cyclopentolate
(willing Cycloperitolate Eye drops 1 %, single dose (preservative	i ilee) to be dells	sieu i Aprii 202	2)
TROPICAMIDE			
TROPICAMIDE * Eye drops 0.5%	7.15	15 ml OP	✓ Mydriacyl

For acetylcysteine eye drops refer Standard Formulae, page 242			
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 Fully Brand or
(Manufacturer's Price) Subsidised Generic
\$ Per ✓ Manufacturer

Preservative Free Ocular Lubricants

⇒SA1388 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 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 SA1388 above – Retail pharm	nacy		
Ophthalmic gel 0.3%, 0.5 g	8.25	30	✓ Poly-Gel
MACROGOL 400 AND PROPYLENE GLYCOL - Special Authority	see SA1388 a	above – Retail	pharmacy
Eye drops 0.4% and propylene glycol 0.3%, 0.4 ml	4.30	24	Systane Unit Dose
SODIUM HYALURONATE [HYALURONIC ACID] - Special Authori	ty see SA1388	3 above – Ret	ail pharmacy
Eye drops 1 mg per ml	13.85	10 ml OP	✓ Hylo-Fresh
Hylo-Fresh has a 6 month expiry after opening. The Pharm	nacy Procedur	es Manual res	striction allowing one bottle per
month is not relevant and therefore only the prescribed dos	age to the nea	arest OP may	be claimed.

Other Eye Preparations

NAPHAZOLINE HYDROCHLORIDE * Eye drops 0.1%4.15	15 ml OP	✓ Naphcon Forte
OLOPATADINE Eye drops 0.1%2.20	5 ml OP	✓ Olopatadine Teva
PARAFFIN LIQUID WITH WOOL FAT * Eye oint 3% with wool fat 3%	3.5 g OP	✓ Poly-Visc
RETINOL PALMITATE Eye oint 138 mcg per g3.80	5 g OP	✓ VitA-POS



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

Various

PHARMACY SERVICES

May only be claimed once per patient.

- 1 fee **✓ BSF Clomipramine**
 - ✓ BSF Febuxostat multichem
 - ✓ BSF Lopinavir/
 Ritonavir Mylan
- a) The Pharmacode for BSF Febuxostat multichem is 2621967 see also page 116
- b) The Pharmacode for BSF Lopinavir/Ritonavir Mylan is 2621959 see also page 106
- c) The Pharmacode for BSF Clomipramine Teva is 2630915 see also page 125

(BSF Clomipramine Teva Brand switch fee to be delisted 1 May 2022)

(BSF Febuxostat multichem Brand switch fee to be delisted 1 April 2022)

(BSF Lopinavir/Ritonavir Mylan Brand switch fee to be delisted 1 May 2022)

Agents Used in the Treatment of Poisonings

Antidotes

ACFTYI	1.00	ı⊢ın	

Pharma \$29

NALOXONE HYDROCHLORIDE

- a) Up to 5 inj available on a PSO
- b) Only on a PSO

Removal and Elimination

CHARCOAL

- 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	✓ Exiade

⇒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:

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

continued...

- 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
- 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).</p>

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:

Fither:

- 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.

DESFERRIOXAMINE MESILATE ★ Inj 500 mg vial	151.31	10	✓ DBL Desferrioxamine Mesylate for Inj BP
SODIUM CALCIUM EDETATE * Inj 200 mg per ml, 5 ml	53.31	6	
, , ,	156.71)		Calcium Disodium Versenate

Standard Formulae

Statiualu Foliliulae			
ACETYLCYSTEINE EYE DROPS Acetylcysteine inj 200 mg per ml, 10 ml Suitable eye drop base	qs qs	PHENOBARBITONE ORAL LIQUID Phenobarbitone Sodium Glycerol BP Water	1 g 70 ml to 100 ml
CODEINE LINCTUS (3 mg per 5 ml) Codeine phosphate Glycerol Preservative Water	60 mg 40 ml qs to 100 ml	PHENOBARBITONE SODIUM PAEDIATRIC ORAL mg per ml) Phenobarbitone Sodium Glycerol BP Water	
CODEINE LINCTUS (15 mg per 5 ml) Codeine phosphate Glycerol Preservative Water	300 mg 40 ml qs to 100 ml	PILOCARPINE ORAL LIQUID Pilocarpine 4% eye drops Preservative Water	qs qs to 500 ml
FOLINIC MOUTHWASH Calcium folinate 15 mg tab Preservative Water (Preservative should be used if quantity supplied is f than 5 days. Maximum 500 ml per prescription.)	1 tab qs to 500 ml for more	(Preservative should be used if quantity supplied is than 5 days.) SALIVA SUBSTITUTE FORMULA Methylcellulose Preservative Water	5 g qs to 500 ml
METHADONE MIXTURE Methadone powder Glycerol Water	qs qs to 100 ml	(Preservative should be used if quantity supplied is than 5 days. Maximum 500 ml per prescription.) SODIUM CHLORIDE ORAL LIQUID Sodium chloride inj 23.4%, 20 ml Water	for more qs qs
METHYL HYDROXYBENZOATE 10% SOLUTION Methyl hydroxybenzoate Propylene glycol (Use 1 ml of the 10% solution per 100 ml of oral liqui	10 g to 100 ml id mixture)	(Only funded if prescribed for treatment of hyponatr VANCOMYCIN ORAL SOLUTION (50 mg per ml) Vancomycin 500 mg injection Glycerol BP	
OMEPRAZOLE SUSPENSION Omeprazole capules or powder Sodium bicarbonate powder BP Water	qs 8.4 g to 100 ml	Water (Only funded if prescribed for treatment of Clostridiu following metronidazole failure)	to 100 ml

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer

	\$	Per
Extemporaneously Compounded Preparations and	Galenical	ls

CODEINE PHOSPHATE - Safety medicine; prescriber may determine dispensing frequency

(90.09)

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.

✓ PSM 100 ml

COMPOUND HYDROXYBENZOATE - Only in combination

Only in extemporaneously compounded oral mixtures.

100 ml ✓ Midwest

GLYCERIN WITH SODIUM SACCHARIN - Only in combination

Only in combination with Ora-Plus.

473 ml **Ora-Sweet SF**

GLYCERIN WITH SUCROSE - Only in combination

Only in combination with Ora-Plus.

Suspension.......30.95

473 ml **Ora-Sweet**

GI YCFROI

Powder

Only in extemporaneously compounded oral liquid preparations.

500 ml ✓ healthE Glycerol BP

✓ AET

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).

7 9/

/ .84	1 g	♥ AFI
0.00	0.5	
8.98	25 g	✓ <u>Midwest</u>
36.95	100 a	✓ MidWest
	473 ml	✓ Ora-Plus
- Only in cor	nbination	
30.95	473 ml	✓ Ora-Blend SF
ombination		
30.95	473 ml	✓ Ora-Blend
52.50	10 g	✓ MidWest
325.00	100 g	✓ MidWest
10% solution.		
11.25	500 ml	✓ Midwest
10.05	500 g	✓ Midwest
	. 3	
	30.95 ombination 30.95 52.50 325.00 10% solution. 11.25	8.98 25 g 36.95 100 g 30.95 473 ml - Only in combination 30.95 473 ml ombination 30.95 473 ml 52.50 10 g 325.00 100 g

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

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy (Manufacturer's Price \$) Sub	Fully osidised	Brand or Generic Manufacturer	
SYRUP (PHARMACEUTICAL GRADE) – Only in combination Only in extemporaneously compounded oral liquid preparatio		500 ml	<u> </u>	1idwest	
WATER Tap - Only in combination	0.00	1 ml	✓ Ta	ap water	

Subsidy (Manufacturer's Price) \$

Subsidised Per

Fully

Brand or Generic Manufacturer

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:

Fither:

- 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:

- 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]

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...

✓ fully subsidised 245



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

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.

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...

- 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:

- 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 A	uthority see SA1524 above – Hospitai pha	armacy [HP3]	
Powder	7.90	225 g OP	✓ Protifar
	8.95		✓ Resource
		•	Beneprotein

✓ fully subsidised 247

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

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 s	ee SA1095 above -	- Hospital pharm	nacy [HP3]
Liquid	3.75	500 ml OP	✓ Glucerna Select
·	7.50	1,000 ml OP	Diason RTH
DIABETIC ORAL FEED 1KCAL/ML - Special Authority see S	A1095 above - Ho	spital pharmacy	[HP3]
Liquid (strawberry)	1.50	200 ml OP	✓ Diasip
Liquid (vanilla)		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]

Powder60.48 400 g OP

✓ Monogen

Subsidy (Manufacturer's Price) \$ Fully Subsidised Per

Brand or Generic Manufacturer

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]

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]

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...

✓ fully subsidised 249

Subsidy	Fully	Brand or
(Manufacturer's	s Price) Subsidised	Generic
\$	Per 🗸	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 Liquid		the previous page 500 ml OP	ge – Hospital pharmacy [HP3] ✓ Nutrini Energy RTH
PAEDIATRIC ENTERAL FEED 1KCAL/ML - Special Authority see S/Liquid		e previous page 500 ml OP	 Hospital pharmacy [HP3] Nutrini RTH Pediasure RTH
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special pharmacy [HP3]	Authority se	e SA1379 on the	e previous page – Hospital
Liquid	6.00	500 ml OP	✓ Nutrini Energy Multi Fibre
PAEDIATRIC ORAL FEED 1.5KCAL/ML – Special Authority see SA1: Liquid (strawberry) Liquid (vanilla)	1.60	orevious page – 200 ml OP 200 ml OP	Hospital pharmacy [HP3] Fortini Fortini
PAEDIATRIC ORAL FEED 1KCAL/ML - Special Authority see SA137 Liquid (chocolate) Liquid (strawberry) Liquid (vanilla)	1.07 1.07	evious page – H 200 ml OP 200 ml OP 200 ml OP 250 ml OP	ospital pharmacy [HP3] ✓ Pediasure ✓ Pediasure ✓ Pediasure ✓ Pediasure ✓ Pediasure
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML - Special Auth pharmacy [HP3]	ority see SA	A1379 on the pre	evious page – Hospital
Liquid (unflavoured) Liquid (chocolate) Liquid (strawberry) Liquid (vanilla)	1.60 1.60	200 ml OP 200 ml OP 200 ml OP 200 ml OP	 ✓ Fortini Multi Fibre ✓ Fortini Multi Fibre ✓ Fortini Multi Fibre ✓ Fortini Multi Fibre
PEPTIDE-BASED ORAL FEED – Special Authority see SA1379 on the Powder		page – Hospital 400 g OP	pharmacy [HP3] 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 pharma	cy [HP3]
Liquid	6.08	500 ml OP	✓ Nepro HP RTH

	Subsidy (Manufacturer's F \$	Price) Subsi Per	Fully idised	
RENAL ORAL FEED 1.8 KCAL/ML – Special Authority see SA1 Liquid		ous page – Hos 220 ml OP		oharmacy [HP3] Nepro HP (strawberry) Nepro HP (vanilla)
RENAL ORAL FEED 2 KCAL/ML - Special Authority see SA110	01 on the previou	ıs page – Hospit	tal ph	armacy [HP3]
Liquid	2.88	237 ml OP		
	(3.31)			NovaSource Renal
Liquid, 200 ml bottle	11.52	4 OP		
	(13.24)			NovaSource Renal
Liquid (apricot) 125 ml		4 OP	1	Renilon 7.5
Liquid (caramel) 125 ml(NovaSource Renal Liquid to be delisted 1 September 2022)	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 - Liquid		SA1377 above 1,000 ml OP	
ORAL ELEMENTAL FEED 0.8KCAL/ML - Special Authority			
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 se	ee SA1377 above – F	Hospital pharma	acy [HP3]
Powder (unflavoured)	4.50	80 g OP	✓ Vivonex TEN
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML - Special A	Authority see SA1377	above – Hosp	ital pharmacy [HP3]
Liquid	12.04	1.000 ml OP	✓ Pentisorb

Subsidy (Manufacturer's Price)

Fully Subsidised Brand or Generic Manufacturer

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 ab	ove -	 Hospital pharmacy [HP3]
Liquid	4.00	500 ml OP	1	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:

Subsidy (Manufacturer's Price)	S	Fully	Brand or Generic	
\$	Per	1	Manufacturer	

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		Fully	Brand or	
(Manufacturer's Pri	ce)	Subsidised	Generic	
\$	Pe	er 🗸	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 \$		Fully Brand or dised Generic Manufacturer
ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1859 Liquid		lospital pharmac 250 ml OP 1,000 ml OP	y [HP3] ✓ Ensure Plus HN ✓ Ensure Plus RTH ✓ Nutrison Energy
ENTERAL FEED 1KCAL/ML – Special Authority see SA1859 or Liquid		spital pharmacy 250 ml OP 1,000 ml OP	HP3] ✓ Isosource Standard ✓ Nutrison Standard RTH ✓ Osmolite RTH
ENTERAL FEED WITH FIBRE 0.83 KCAL/ML - Special Author Liquid	,	on page 252 – Ho 1,000 ml OP	ospital pharmacy [HP3] Nutrison 800 Complete Multi Fibre
ENTERAL FEED WITH FIBRE 1 KCAL/ML – Special Authority s		oage 252 – Hosp 1,000 ml OP	ital pharmacy [HP3] ✓ Jevity RTH ✓ Nutrison Multi Fibre
ENTERAL FEED WITH FIBRE 1.2KCAL/ML - Special Authority Liquid		page 252 – Hos 1,000 ml OP	pital pharmacy [HP3] ✓ Jevity Plus
ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority Liquid		page 252 – Hos 1,000 ml OP	pital pharmacy [HP3] ✓ Jevity HiCal RTH ✓ Nutrison Energy Multi Fibre
ORAL FEED (POWDER) – Special Authority see SA1859 on pa Powder (chocolate)	•	al pharmacy [HP 840 g OP	3] ✓ Sustagen Hospital Formula
Powder (vanilla)	26.00 14.00	850 g OP 840 g OP	✓ Ensure ✓ Sustagen Hospital Formula Active
	26.00	850 g OP	✓ Ensure

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

ORAL FEED 1.5KCAL/ML - Special Authority see SA1859 on page 252 - 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	200 ml OP	
	(1.26) (1.26)		Ensure Plus Fortisip
Liquid (chocolate) – Higher subsidy of \$1.26 per 200 ml with Endorsement	0.72	200 ml OP	
	(1.26) (1.26)	200 0.	Ensure Plus Fortisip
Liquid (fruit of the forest) — Higher subsidy of \$1.26 per 200 ml with Endorsement		200 ml OP	
Liquid (strawberry) – Higher subsidy of \$1.26 per 200 ml with	(1.26)		Ensure Plus
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	237 ml OP	
	(1.33) 0.72	200 ml OP	Ensure Plus
	(1.26) (1.26)		Ensure Plus Fortisip

ORAL FEED WITH FIBRE 1.5 KCAL/ML - Special Authority see SA1859 on page 252 - 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	200 ml OP	
	(1.26)		Fortisip Multi Fibre
Liquid (strawberry) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre
Liquid (vanilla) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisin 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.

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0.1.1		F "	D 1	
Subsidy		Fully	Brand or	
(Manufacturer's Price)	Sı	ubsidised	Generic	
\$	Per	✓	Manufacturer	

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 p	age - Hospital p	harmacy [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

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.

SPECIAL FOODS

	Subsidy (Manufacturer's Price \$	Subs Per	Fully sidised	Brand or Generic Manufacturer
FOOD THICKENER – Special Authority see SA1106 on the pre	6.53 3	l pharmacy 00 g OP 80 g OP	✓ N ✓ F	lutilis eed 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 SA172 Powder		narmacy [HP3] 1,000 g OP	
	(5.15)	.,000 g C.	Healtheries Simple Baking Mix
GLUTEN FREE BREAD MIX - Special Authority see SA1729	above – Hospital pha	armacy [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 abo	ve – Hospital pharma	cy [HP3]	
Powder	5.62	2,000 g OP	
	(18.10)	-	Horleys Flour

	Subsidy (Manufacturer's Pr		Fully sidised	Brand or Generic
	\$	Per		Manufacturer
GLUTEN FREE PASTA - Special Authority see SA1729 on the	previous page – H	lospital pharm	nacy [HF	23]
Buckwheat Spirals	2.00	250 g OP		•
	(3.11)		0	rgran
Corn and Vegetable Shells	2.00	250 g OP		
	(2.92)		0	rgran
Corn and Vegetable Spirals	2.00	250 g OP		
	(2.92)		0	rgran
Rice and Corn Lasagne Sheets	1.60	200 g OP		
	(3.82)		0	rgran
Rice and Corn Macaroni	2.00	250 g OP		
	(2.92)		0	rgran
Rice and Corn Penne	2.00	250 g OP		
	(2.92)		0	rgran
Rice and Maize Pasta Spirals	2.00	250 g OP		
	(2.92)		0	rgran
Rice and Millet Spirals	2.00	250 g OP		
	(3.11)		0	rgran
Rice and corn spaghetti noodles	2.00	375 g OP		
	(2.92)		0	rgran
Vegetable and Rice Spirals	2.00	250 g OP		
	(2.92)		0	rgran
Italian long style spaghetti	2.00	220 g OP		
	(3.11)		0	rgran

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

Supplements For MSUD

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE - Special Authority see SA1108 above - Hospital pharmacy [HP3]

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

Supplements For PKU

AMINOACID FORMULA WITHOUT PHENYLALANINE – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]

annacy [nro]			
Tabs	99.00	75 OP	✓ Phlexy 10
Powder (orange) 36 g sachet		30	✓ PKU Ánamix Junior Orange
Powder (berry) 28 g sachets	936.00	30	✓ PKU Lophlex Powder
Powder (chocolate) 36 g sachet	393.00	30	✓ PKU Anamix Junior
Powder (orange) 28 g sachets	936.00	30	Chocolate ✓ PKU Lophlex
Powder (unflavoured) 28 g sachets	936.00	30	Powder ✓ PKU Lophlex
Powder (unflavoured) 36 g sachets		30	Powder ✓ 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)		500 g OP	XP Maxamum
Liquid (berry)		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		30 OP	✓ PKU Lophlex LQ 20
Oral semi-solid (berries) 109 g		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

Foods

LOW PROTEIN BAKING MIX - Special Authority see SA1108 on the previous page - Hospital pharmacy [HP3]

Powder8.22 500 g OP ✓ Loprofin Mix

LOW PROTEIN PASTA - Special Authority see SA1108 on the previous page - 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		250 g OP	✓ Loprofin
Penne	11.91	500 g OP	✓ Loprofin
Spaghetti	11.91	500 g OP	✓ Loprofin
Spirals	11.91	500 a OP	✓ Loprofin

Subsidy (Manufacturer's Price) \$

Subsidised Per

Fully

Brand or Generic Manufacturer

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.

Gastrointestinal and Other Malabsorptive Problems

AMINO ACID FOHMULA — Special Authority see SA2092 below — Hospital p Powder43.60	,	✓ Alfamino
Powder (unflavoured)53.00	400 g OP	✓ Alfamino Junio ✓ Elecare ✓ Elecare LCP ✓ Neocate Gold
		✓ Neocate Junior Unflavoured
Powder (vanilla)53.00	400 g OP	 ✓ Neocate SYNEO ✓ Elecare ✓ Neocate Junior ✓ Vanilla

⇒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
- 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

continued...

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

continued...

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:

Roth:

- 1 Fither:
 - 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
 - 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

continued...

Subsidy	Fully	Brand or	
(Manufacturer's Price)	Subsidised	Generic	
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- 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 Auth	nority see SA1953 below -	Hospital pharr	nacy [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
 - 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

continued...

SPECIAL FOODS

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- 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	Aptamil AllerPro SYNEO 1
			✓ Aptamil AllerPro SYNEO 2

⇒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
- 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.

continued...

Subsidy (Manufacturer's Price	2)	Fully Subsidised	Brand or Generic	
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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] Liquid......2.35 125 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.

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

IGITIAT LOW CANDOTT DITATE TO NIVIOLA - Special Authority see	5 OMITOT a	ibove – i tetali pi	lailliacy
Powder (unflavoured)	.35.50	300 g OP	✓ KetoCal 4:1
		•	✓ Ketocal 3:1
Powder (vanilla)	.35.50	300 a OP	✓ KetoCal 4:1

SECTION I: NATIONAL IMMUNISATION SCHEDULE

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer **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 egual 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 DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE - [Xpharm] 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. Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous 10 **Boostrix Boostrix** 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 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. Ini 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

Infanrix IPV

10

Fully

✓ <u>Havrix</u>✓ Havrix Junior

Brand or

Subsidy

	(Manufacturer's Price)	Subs Per	idised	Generic Manufacturer
DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AI [Xpharm] Funded for patients meeting any of the following criteria: 1) Up to four doses for children up to and under the age of 2) An additional four doses (as appropriate) are funded for 10 who are patients post haematopoietic stem cell trans post solid organ transplant, renal dialysis and other sev. 3) Up to five doses for children up to and under the age of Note: A course of up-to four vaccines is funded for catch up to complete full primary immunisation. Please refer to the Improgrammes. 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	f 10 for primary immur r (re-)immunisation for splantation, or chemo erely immunosuppre 10 receiving solid or programmes for child munisation Handboo	unisation; or children otherapy; passive regirgan transporter (up to	or up to ar re or po nens; or olantatio and un ppropria	nd under the age of ost splenectomy; pre- or on. der the age of 10 years)
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-)im transplantation, or chemotherapy; functional asplenic; p or post cochlear implants, renal dialysis and other seven 3) For use in testing for primary immunodeficiency disease paediatrician.	nmunisation for patier ire or post splenector rely immunosuppress	my; pre- or sive regim	ematop post so	oietic stem cell olid organ transplant, pre-
Haemophilus Influenzae type B polysaccharide 10 mcg conjugated to tetanus toxoid as carrier protein 20-40 mcg prefilled syringe plus vial 0.5 ml 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 di 3) One dose of vaccine for close contacts of known hepati	0.00	1	√ H	iberix

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Inj 10 mo	B RECOMBINANT VACCINE - [Xpharm] cg per 0.5 ml prefilled syringe		1	√ E	Engerix-B
1) 2) 3) 4) 5) 6) 7)	ded for patients meeting any of the following criteri for household or sexual contacts of known acute for children born to mothers who are hepatitis B s for children up to and under the age of 18 years i serology and require additional vaccination or rec for HIV positive patients; or for hepatitis C positive patients; or for patients following non-consensual sexual inte for patients following immunosuppression; or for solid organ transplant patients; or for post-haematopoietic stem cell transplant (HSC)	hepatitis B patients or h surface antigen (HBsAg nclusive who are considurire a primary course of rcourse; or	, pos derec	itive; or I not to have	e achieved a positive
10)	following needle stick injury.				
	cg per 1 ml prefilled syringeded for patients meeting any of the following criteri		1	√ <u>E</u>	Engerix-B
2) 3) 4) 5) 6) 7) 8) 9) 10) 11)	for household or sexual contacts of known acute for children born to mothers who are hepatitis B s for children up to and under the age of 18 years i serology and require additional vaccination or rec for HIV positive patients; or for hepatitis C positive patients; or for patients following non-consensual sexual inte for patients following immunosuppression; or for solid organ transplant patients; or for post-haematopoietic stem cell transplant (HSC following needle stick injury; or for dialysis patients; or for liver or kidney transplant patients.	surface antigen (HBsAg nclusive who are considurie a primary course of rcourse; or) pos derec	itive; or I not to have	•
Any of th	PILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND ne following:	,	- [Xpl	narm]	
2) Ma 1 2	eximum of two doses for children aged 14 years an eximum of three doses for patients meeting any of the People aged 15 to 26 years inclusive; or either: People aged 9 to 26 years inclusive 1) Confirmed HIV infection; or 2) Transplant (including stem cell) patients: eximum of four doses for people aged 9 to 26 years	he following criteria: or	nerap	у	
Inj 270 m	ncg in 0.5 ml syringe	0.00	10	√ <u>(</u>	Gardasil 9

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

INFLUENZA VACCINE

Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)

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) cerebo-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 from the Funder 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 Fully Brand or (Manufacturer's Price) Subsidised Generic
\$ Per ✔ Manufacturer

- a) Only on a prescription
- b) No patient co-payment payable

С

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 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) cerebo-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
- c) children 3 and 4 years of age (inclusive) who 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) Contractors will be entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with their DHB 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) \$	S Per	Fully ubsidised	Brand or Generic Manufacturer	
*				

MEASLES, MUMPS AND BUBELLA VACCINE

- a) Only on a prescription
- b) No patient co-payment payable

c)

A) Measles, mumps and rubella vaccine

A maximum of two doses for any patient meeting the following criteria:

- 1) For primary vaccination in children; or
- 2) For revaccination following immunosuppression; or
- 3) For any individual susceptible to measles, mumps or rubella; or
- 4) 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.

- B) Contractors will be entitled to claim payment from the Funder for the supply of measles, mumps and rubella vaccine to patients eligible under the above criteria pursuant to their contract with their DHB for subsidised immunisation, and they may only do so in respect of the measles, mumps and rubella vaccine listed in the Pharmaceutical Schedule.
- C) 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

MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJUGATE VACCINE - [Xpharm]

Fither:

- 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
 - 2) One dose for close contacts of meningococcal cases of any group; or
 - 3) One dose for person 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 person pre- and post-immunosuppression*; or
- B) Both:
 - 1) Person is aged between 13 and 25 years, inclusive; and
 - 2) Either:
 - i) 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
 - ii) 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

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer 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*; or 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. ✓ 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. ✓ Neisvac-C 1 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 Ini 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

✓ Synflorix

10

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

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
 - I) 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
- 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	3
Inj 30.	B mcg of pneumococcal polysaccharide serotypes 1, 3, 4,	

5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5ml		
syringe	10	✓ Prevenar 13
, -	1	✓ Prevenar 13

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			Subsidy (Manufacturer's Price) \$	Sı Per	Fully ubsidised	Brand or Generic Manufacturer
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 oral failure, or nephrotic syndrome; or v) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplator or vi) with corelar implants or intracranial shunts; or viii) with corebrospinal 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 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 xii with diabetes; or xiii) 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)		PV23) POLYSACCHARIDE VACCINE -	[Xpharm]			
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 transpla 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 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 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)	Up to three contemplement	py; pre- or post-splenectomy or with functi deficiency (acquired or inherited), cochle	onal asplenia, pre- or p	ost-so	lid organ t	ransplant, renal dialysis,
in mmunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or ii) with HIV infection; or iv) with primary immune deficiencies; or iii) with HIV infection; or v) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transpla 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 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)	a) Patient b) Treatm	t is a child under 18 years for (re-)immunis nent is for a maximum of two doses; and	sation; and			
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 transplator 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 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 Down syndrome; 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)	, ,	•	n therapy, vaccinate wh	nen the	re is expe	cted to be a sufficient
iv) with renal failure, or nephrotic syndrome; or y) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplator 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 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 Down syndrome; 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)	ir ii) v	mmune response; or vith primary immune deficiencies; or			. o io onpo	
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 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)	iv) w	vith renal failure, or nephrotic syndrome; o		uding h	naematopo	vietic stem cell transplant);
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 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 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)	vi) v	vith cochlear implants or intracranial shunt	s; 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)	viii) r	eceiving corticosteroid therapy for more th				
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)		5 5 7	asthma treated with hig	ah-dose	e corticoste	eroid therapy); 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)	x) p	re term infants, born before 28 weeks ges	tation; or	,		13/
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)	xii) w	vith diabetes; or	, 01			
23 pneumococcal serotype)	,		unctional asplenia.			
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					4 -	
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>P</u>	neumovax 23
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			j :			
Note: Please refer to the Immunisation Handbook for appropriate schedule for catch-up programmes. Inj 80D antigen units in 0.5 ml syringe	•		•			
Inj 80D antigen units in 0.5 ml syringe	,	•				
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					0	
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	, ,	, ,		'	• 11	OL
no vaccination being administered to children aged 24 weeks or over. Oral susp live attenuated human rotavirus						
Oral susp live attenuated human rotavirus	,	•	•			
·	no vaccination	on being administered to children aged 24	weeks or over.			
1,000,000 CCID50 per dose, prefilled oral applicator	Oral susp live atte	nuated human rotavirus				
	1,000,000 CC	CID50 per dose, prefilled oral applicator	0.00	10	✓ <u>R</u>	<u>otarix</u>

	NATIONAL	IMMUNI	SATI	ON SCHEDULE
	Subsidy (Manufacturer's Price)	Subs Per	Fully idised	Brand or Generic Manufacturer
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 y 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 ii) with deteriorating renal function before tran iii) prior to solid organ transplant; or iv) prior to any elective immunosuppression*, v) for post exposure prophylaxis who are imm b) For patients at least 2 years after bone marrow to c) For patients at least 6 months after completion of d) For HIV positive non immune to varicella with mile e) For patients with inborn errors of metabolism at revaricella, or f) For household contacts of paediatric patients who	years old on or after 1 be be candidates for trasplantation; or or une competent inpatic fransplantation, on adv from the competent impatic from the competent impatic from the competent immunisk of major metabolic or are immunocomproi	ents.; or ice of their dvice of the osuppress decomper mised, or u	on; or special sir specion on a	alist, or cialist, or advice of HIV specialist, or , with no clinical history of bing a procedure leading to
immune compromise where the household conta g) For household contacts of adult patients who hav immunocompromised, or undergoing a procedure has no clinical history of varicella.	ve no clinical history o	f varicella a	and wh	o are severely
* immunosuppression due to steroid or other immunosuppre 28 days	essive therapy must be	e for a treat	tment p	period of greater than
Inj 1350 PFU prefilled syringe	0.00	1 10	_	<u>'arivax</u> 'arivax
VARICELLA ZOSTER VIRUS (OKA STRAIN) LIVE ATTENUATI Funded for patients meeting the following criteria: 1) One dose for all people aged 65 years	ED VACCINE [SHING	LES VACO	: [BNIC	- [Xpharm]
Inj 19,400 PFU prefilled syringe plus vial	0.00	1 10		ostavax ostavax
Diagnostic Agents				
TUBERCULIN PPD [MANTOUX] TEST - [Xpharm] Inj 5 TU per 0.1 ml, 1 ml vial	0.00	1	✓ <u>T</u>	ubersol

- Symbols -	Albendazole	89	Anagrelide hydrochloride	150
UK Synacthen80	Albey		Analgesics	
3TC106	Albustix	77	Anastrozole	16
- A -	Alchemy Oxybutynin	76	Anatrole	
A-Scabies68	Aldurazyme	29	Andriol Testocaps	8
Abacavir sulphate105	Alecensa	157	Androderm	8
Abacavir sulphate with	Alectinib	157	Anoro Ellipta	230
lamivudine105	Alendronate sodium	111	Antabuse	143
Abiraterone acetate164	Alendronate sodium with		Antacids and Antiflatulents	
Acarbose11	colecalciferol		Anthelmintics	
Accarb11	Alfacalcidol		Antiacne Preparations	
Accuretic 1048	Alfamino		Antiallergy Preparations	
Accuretic 2048	Alfamino Junior		Antianaemics	3
Acetazolamide237	Alginic acid		Antiandrogen Oral	
Acetec47	Alglucosidase alfa		Contraceptives	
Acetic acid with hydroxyquinoline and	Alkeran		Antiarrhythmics	
ricinoleic acid75	Alkeran S29		Antibacterials	
Acetylcysteine240	Allersoothe		Antibacterials Topical	
Aci-Jel75	Allmercap		Anticholinergic Agents	
Aciclovir	Allopurinol		Anticholinesterases	
Infection 101	Alpha-Adrenoceptor Blockers		Antidepressants	
Sensory235	Alpha-Keri Lotion		Antidiarrhoeals	
Acidex6	Alphamox		Antiepilepsy Drugs	
Acipimox54	Alphamox 125		Antifibrinolytics, Haemostatics and	
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Actrapid	Amantadine hydrochloride		Antihypotensives	
Actrapid Penfill10	Ambrisentan		Antimalarials	
Acupan	Ambrisentan Mylan		Antimigraine Preparations	
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Adapalene	Amiloride hydrochloride with furosemide	E 2	AntipsychoticsAntiretrovirals	
ADR Cartridge 1.8	Amiloride hydrochloride with	33	Antirheumatoid Agents	
Advantan	hydrochlorothiazide	54	Antispasmodics and Other Agents	! !
Advate41	Aminophylline		Altering Gut Motility	9
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Afinitor	Amisulpride		Antithymocyte globulin	
Aflibercept	Amisulpride Mylan		(equine)	17
Afluria Quad	Amitriptyline		Antitrichomonal Agents	
(2022 formulation)	Amlodipine		Antituberculotics and	
Afluria Quad Junior	Amneal		Antileprotics	g
(2022 formulation)	Amorolfine		Antiulcerants	
AFT-Pyrazinamide100	Amoxicillin		Antivirals	
Agents Affecting the	Amoxicillin with clavulanic acid		Anxiolytics	
Renin-Angiotensin System 47	Amphotericin B		Anzatax	
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Apo-Diclo SR	110	ATGAM	175	G]	9
Apo-Diltiazem CD	52	Ativan	135	Beta Cream	
Apo-Doxazosin	47	Atomoxetine	138	Beta Ointment	6
Apo-Folic Acid		Atorvastatin	54	Beta Scalp	70
Apo-Megestrol	165	Atropine sulphate		Beta-Adrenoceptor Agonists	22
Apo-Oxybutynin		Cardiovascular	49	Beta-Adrenoceptor Blockers	5
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Apo-Pyridoxine		Aubagio	137	Betaine	
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Aprepitant		AutoSoft 90	23	calcipotriol	6
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Aptamil AllerPro SYNEO 2		Avonex Pen	136	Betamethasone valerate6	3, 70
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Arrow - Lattim	238	B-D Micro-Fine	15	Bezalip Retard	
Arrow-Amitriptyline	125	B-D Ultra Fine	16	Bicalutamide	
Arrow-Bendrofluazide		B-D Ultra Fine II	16	Bicillin LA	9
Arrow-Brimonidine		Bacillus Calmette-Guerin (BCG)		BiCNU	140
Arrow-Diazepam		vaccine	175	Bicnu Heritage	
Arrow-Doxorubicin		Bacillus Calmette-Guerin		Bile and Liver Therapy	
Arrow-Losartan &		vaccine	266	Biltricide	
Hydrochlorothiazide	48	Baclofen		Bimatoprost	
Arrow-Norfloxacin		Bactroban		Bimatoprost Multichem	
Arrow-Ornidazole		Balance		Binarex	
Arrow-Quinapril 10		Barrier Creams and Emollients		Binocrit	
Arrow-Quinapril 20		Basic AquaCream		Biodone	
Arrow-Quinapril 5		BCG Vaccine		Biodone Extra Forte	
Arrow-Roxithromycin		Beclazone 100		Biodone Forte	
Arrow-Timolol		Beclazone 250		Bisacodyl	
Arrow-Topiramate	129	Beclazone 50	227	Bisoprolol fumarate	
Arrow-Tramadol		Beclomethasone dipropionate		Bisoprolol Mylan	50
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Atenolol		Benztrop		impaired)	1!
Atenolol AFT		Benzydamine hydrochloride		Blood Ketone Diagnostic Test	
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Clopidogrel Multichem		Crystaderm	61	DBL Leucovorin Calcium	
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Nervous		Cytotec		Dermol	
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Colchicine		- D -		Desmopressin	
Colecalciferol		D-Penamine	111	Desmopressin acetate	
Colestid		Dabigatran		Desmopressin-PH&T	
Colestipol hydrochloride		Dacarbazine		Desuric	
Colgout		Dacarbazine APP		Detection of Substances in	
Colifoam		Dactinomycin [Actinomycin D]		Urine	77
Colistin sulphomethate		Daivobet		Dexamethasone	
Colistin-Link		Daivonex		Hormone	79
Collodion flexible		Daktarin		Sensory	
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