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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.

#### Pharmac's role:

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

Pae Ora (Healthy Futures) Act 2022

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

Further information about Pharmac and the way we make funding decisions can be found on the Pharmac website at <a href="https://pharmac.govt.nz/about">https://pharmac.govt.nz/about</a>.

# Purpose of the Pharmaceutical Schedule

The purpose of the Schedule is to list:

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

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

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

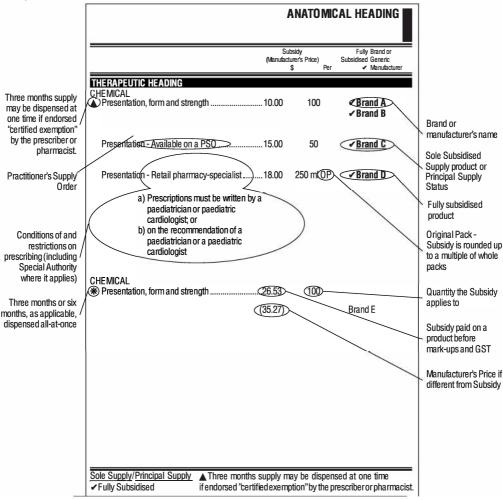
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

The index lists both chemical entities and product brand names.

# **Explaining pharmaceutical entries**

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

#### Example



# Glossary

#### Units of Measure

gram g	
kilogram kg	
international unit iu	

### Abbreviations

Capsule Cream Device Dispersible Effervescent Emulsion	Amp Cap Crm Dev Disp Eff Emul EC
Enteric Coated	EC

microgram me	cg
milligramn	ng
millilitreı	ml

millimole	mmol
unit	u

Gelatinous	Gel	SolutionSoln
Granules	Gran	SuppositorySupp
Infusion	Inf	TabletTab
Injection	Inj	Tincture Tinc
Liquid	Liq	Trans Dermal Delivery
Long Acting	LA	SystemTDDS
Ointment	Oint	-
Sachet	Sach	

Read the General Rules : https://pharmac.govt.nz/section-a.

## SECTION B: ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
Antacids and Antiflatulents				
Antacids and Reflux Barrier Agents				
LGINIC ACID Sodium alginate 225 mg and magnesium alginate 87.5 mg per sachet		30	v	Gaviscon Infant
ODIUM ALGINATE Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour		60		Gaviscon Extra
<ul> <li>Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml</li> </ul>	(17.99)	500 m	h	Strength
	(7.50)			Acidex
Phosphate Binding Agents				
LUMINIUM HYDROXIDE Tab 600 mg ALCIUM CARBONATE	12.56	100	1	Alu-Tab
Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) – Subsidy by endorsement		500 m 473 m		Roxane Calcium carbonate PAI \$29
Only when prescribed for patients unable to swallow calci inappropriate and the prescription is endorsed accordingly		ts or v	vhere calc	um carbonate tablets are
Antidiarrhoeals				
Antidiarrhoeals Agents Which Reduce Motility				
	10.75	400 400		Nodia Diamide Relief
Agents Which Reduce Motility         DPERAMIDE HYDROCHLORIDE       – Up to 30 cap available on a         Tab 2 mg       –         Cap 2 mg       –	10.75			
Agents Which Reduce Motility DPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a Tab 2 mg Cap 2 mg Rectal and Colonic Anti-inflammatories	10.75 7.25		•	
Agents Which Reduce Motility OPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a Tab 2 mg Cap 2 mg Cap 2 mg Cap Colonic Anti-inflammatories UDESONIDE Cap modified-release 3 mg – Special Authority see SA1886	10.75 7.25	400 90	, ,	Diamide Relief Budesonide Te Arai
Agents Which Reduce Motility DPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a Tab 2 mg Cap 2 mg Rectal and Colonic Anti-inflammatories UDESONIDE Cap modified-release 3 mg – Special Authority see SA1886 below – Retail pharmacy SA1886 Special Authority for Subsidy itial application — (Crohn's disease) from any relevant practit e following criteria:		400 90	, ,	Diamide Relief Budesonide Te Arai

continued...

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

continued...

- 2.2 Cushingoid habitus; or
- 2.3 Osteoporosis where there is significant risk of fracture; or
- 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.

HYDROCORTISONE AGETATE			
Rectal foam 10%, CFC-Free (14 applications)		15 g OP	<ul> <li>Colifoam</li> </ul>
HYDROCORTISONE ACETATE WITH PRAMOXINE	HYDROCHLORIDE		
Topical aerosol foam, 1% with pramoxine hydrocl	nloride 1%26.55	10 g OP	<ul> <li>Proctofoam S29</li> </ul>
MESALAZINE			
Tab 400 mg		100	Asacol
Tab long-acting 500 mg		100	Pentasa
Tab 800 mg		90	<ul> <li>Asacol</li> </ul>
Tab 1,600 mg		60	Asacol S29
Modified release granules, 1 g		100 OP	Pentasa
Enema 1 g per 100 ml		7	Pentasa
Suppos 500 mg		20	Asacol
Suppos 1 g		28	Pentasa

	Subsidy (Manufacturer's Price	)	Fully Subsidised	
	\$	Per	<ul> <li>Cubbilation</li> <li>✓</li> </ul>	Manufacturer
DLSALAZINE				
Tab 500 mg		60	1	Atnahs
C C				Olsalazine S29
	93.37	100	1	Dipentum
Cap 250 mg		100	✓	Dipentum
ODIUM CROMOGLICATE				
Cap 100 mg	113.35	100	1	Ralicrom
ULFASALAZINE				
€ Tab 500 mg	19.49	100	1	Salazopyrin
€ Tab EC 500 mg		100	1	Salazopyrin EN
Local preparations for Anal and Rectal Disorder	S			
Antihaemorrhoidal Preparations				
LUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIV		IUUAI		
Oint 950 mcg, with fluocortolone pivalate 920 mcg, and cinchocaine hydrochloride 5 mg per g	13.05	30 g C	p 🖌	Ultraproct
Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and		Jugu	· · ·	onapioci
cinchocaine hydrochloride 1 mg	8 61	12	1	Ultraproct
YDROCORTISONE WITH CINCHOCAINE		12	-	onapion
Oint 5 mg with cinchocaine hydrochloride 5 mg per g	15.00	30 g C		Proctosedyl
Suppos 5 mg with cinchocaine hydrochloride 5 mg per g		12		Proctosedyl
				( in the second s
Management of Anal Fissures				
LYCERYL TRINITRATE – Special Authority see SA1329 below Oint 0.2%		30 g C	P 🗸	Rectogesic
SA1329 Special Authority for Subsidy			•	licelegeele
<b>itial application</b> from any relevant practitioner. Approvals valid	l without further ren	ewalu	nless notif	ied where the natient has
hronic anal fissure that has persisted for longer than three weeks		oward	nicoo noti	ied where the patient has
· ·				
Antispasmodics and Other Agents Altering Gut	Motility			
LYCOPYRRONIUM BROMIDE	•			
Inj 200 mcg per ml, 1 ml ampoule – Up to 10 inj available on PSO		5	1	Robinul
		5	•	
YOSCINE BUTYLBROMIDE € Tab 10 mg	0.05	20	1	Hyoscine
€ Tab 10 mg	2.25	20	•	Butylbromide
				(Adiramedica)
Inj 20 mg, 1 ml – Up to 5 inj available on a PSO		5	1	Spazmol
IEBEVERINE HYDROCHLORIDE		Ũ	,	
EDEVENINE HTDROCHLORIDE € Tab 135 mg	8.50	90	1	Colofac
		50		
Antiulcerants				
Antisecretory and Cytoprotective				
IISOPROSTOL – Wastage claimable				
Tab 200 mcg – Up to 120 tab available on a PSO	47.73	120	1	Cytotec
✓ fully subsidised				ed under Section 29
Principal Supply	Sole Subsidised	I Supp	ly	

	Subsidy (Manufacturer's Price)		Fully ubsidised	Brand or Generic
Helicobacter Pylori Eradication	\$	Per		Manufacturer
-				
<ul> <li>CLARITHROMYCIN</li> <li>Tab 500 mg – Subsidy by endorsement</li> <li>a) Maximum of 28 tab per prescription</li> <li>b) Subsidised only if prescribed for helicobacter pylori endorsed in the prescription is considered endorsed if clar inhibitor and either amoxicillin or metronidazole.</li> </ul>	eradication and presc		endorsed	
H2 Antagonists				
FAMOTIDINE – Only on a prescription	4.04	100		
* Tab 20 mg	4.91	100	v F	amotidine Hovid S29
* Tab 40 mg		100	✓ F	amotidine Hovid MY S29
	10.32		✓ F	amotidine Hovid S29
<ul> <li>Inj 10 mg per ml, 4 ml – Subsidy by endorsement</li> <li>Subsidy by endorsement – Subsidised for patients received</li> <li>(Famotidine Hovid S29 Tab 40 mg to be delisted 1 September 2</li> </ul>	iving treatment as par	10 t of palli		ylan S29
Proton Pump Inhibitors				
LANSOPRAZOLE				
* Cap 15 mg * Cap 30 mg		100 100		anzol Relief anzol Relief
OMEPRAZOLE			_	
For omeprazole suspension refer Standard Formulae, page * Cap 10 mg		90		meprazole Teva <u>meprazole actavis</u> 10
* Cap 20 mg	2.02	90		meprazole Teva meprazole actavis 20
* Cap 40 mg	3.18	90		meprazole Teva meprazole actavis 40
<ul> <li>Powder – Only in combination</li> <li>Only in extemporaneously compounded omeprazole sus</li> </ul>		5 g	✓ M	lidwest
Inj 40 mg ampoule with diluent		5		r Reddy's Omeprazole cicure <sup>©29</sup>
PANTOPRAZOLE	1 00	00	1.5	annan Dallaf
<ul> <li>Tab EC 20 mg</li> <li>Tab EC 40 mg</li> </ul>		90 90		anzop Relief anzop Relief
Site Protective Agents				
COLLOIDAL BISMUTH SUBCITRATE Tab 120 mg	14.51	50	✓ G	astrodenol

▲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
SUCRALFATE Tab 1 g	35.50	120		
· · g	(48.28)		(	Carafate

## Bile and Liver Therapy

RIFAXIMIN – Special Authority see SA1461 below – Retail pharmacy

Tab 550 mg ......625.00

#### SA1461 Special Authority for Subsidy

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

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

### Diabetes

### Hyperglycaemic Agents

DIAZOXIDE – Special Authority see SA1320 below – Retail pharmacy		
Cap 25 mg110.00	100	<ul> <li>Proglicem S29</li> </ul>
Cap 100 mg280.00	100	<ul> <li>Proglicem S29</li> </ul>
Oral liq 50 mg per ml620.00	30 ml OP	<ul> <li>e5 Pharma S29</li> </ul>
⇒SA1320 Special Authority for Subsidy		
nitial application from any relevant practitioner. Approvals valid for 12 months v	where used for	the treatment of confirmed
hypoglycaemia caused by hyperinsulinism. Renewal from any relevant practitioner. Approvals valid without further renewal ι	inlace notified	whore the treatment remains
appropriate and the patient is benefiting from treatment.		
GLUCAGON HYDROCHLORIDE		
Inj 1 mg syringe kit – Up to 5 kit available on a PSO	1	<ul> <li>Glucagen Hypokit</li> </ul>
		J J J
Insulin - Short-acting Preparations		
INSULIN NEUTRAL		
Inj human 100 u per ml, 3 ml42.66	5	<ul> <li>Actrapid Penfill</li> </ul>
		<ul> <li>Humulin R</li> </ul>
Inj human 100 u per ml, 10 ml vial25.26	1 OP	<ul> <li>Actrapid</li> <li>Humulin B</li> </ul>
Insulin - Intermediate-acting Preparations		
NSULIN ASPART WITH INSULIN ASPART PROTAMINE		
▲ Inj 100 iu per ml, 3 ml prefilled pen52.15	5	NovoMix 30 FlexPen
NSULIN DEGLUDEC WITH INSULIN ASPART		
▲ Inj degludec 70 u with insulin aspart 30 u, 100 u per ml, 3 ml80.00	5	<ul> <li>Ryzodeg</li> </ul>
		70/30 Penfill
INSULIN ISOPHANE		
Inj human 100 u per ml, 3 ml	5	<ul> <li>Humulin NPH</li> </ul>
A lai human 100 u nav al 10 adviel 17 00		<ul> <li>Protaphane Penfill</li> <li>Illumulin NDU</li> </ul>
Inj human 100 u per ml, 10 ml vial	1 OP	<ul> <li>✓ Humulin NPH</li> <li>✓ Protaphane</li> </ul>

10

Xifaxan

	Subsidy		Fully Brand or	
	(Manufacturer's Price)	Subs	Fully Brand or sidised Generic	
	\$	Per	<ul> <li>Manufacturer</li> </ul>	
INSULIN ISOPHANE WITH INSULIN NEUTRAL				
▲ Inj human with neutral insulin 100 u per ml, 3 ml		5	<ul> <li>Humulin 30/70</li> </ul>	
		U U	✓ PenMix 30	
▲ Inj human with neutral insulin 100 u per ml, 10 ml vial		1 OP	<ul> <li>Humulin 30/70</li> </ul>	
INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
Inj lispro 25% with insulin lispro protamine 75% 100 u per ml, 3 ml		5	Jumping Mix 25	
▲ Inj lispro 50% with insulin lispro protamine 50% 100 u per ml,		5	<ul> <li>Humalog Mix 25</li> </ul>	
<ul> <li>Inj lispro 50% with lispro protamine 50% 100 u per mi, 3 ml</li> </ul>		5	Humalan Mix 50	
5 111		5	<ul> <li>Humalog Mix 50</li> </ul>	
Insulin - Long-acting Preparations				
INSULIN GLARGINE				
▲ Inj 100 u per ml, 10 ml		1	✓ Lantus	
<ul> <li>Inj 100 u per ml, 3 ml</li> </ul>		5	✓ Lantus	
<ul> <li>Inj 100 u per ml, 3 ml disposable pen</li> </ul>		5	✓ Lantus SoloStar	
2 k				
Insulin - Rapid Acting Preparations				
INSULIN ASPART				
▲ Inj 100 u per ml, 10 ml		1	NovoRapid	
▲ Inj 100 u per ml, 3 ml		5	NovoRapid Penfill	
▲ Inj 100 u per ml, 3 ml syringe	51.19	5	NovoRapid FlexPen	
INSULIN GLULISINE			-	
▲ Inj 100 u per ml, 10 ml	27.03	1	<ul> <li>Apidra</li> </ul>	
▲ Inj 100 u per ml, 3 ml		5	✓ Apidra	
▲ Inj 100 u per ml, 3 ml disposable pen		5	<ul> <li>Apidra SoloStar</li> </ul>	
INSULIN LISPRO			•	
▲ Inj 100 u per ml, 3 ml	59 52	5	<ul> <li>Humalog</li> </ul>	
<ul> <li>Inj 100 u per ml, 10 ml vial</li> </ul>		1 OP	✓ Humalog	
Alpha Glucosidase Inhibitors				
ACARBOSE				
* Tab 50 mg	11.20	90	✓ Accarb	
* Tab 100 mg	17.38	90	✓ <u>Accarb</u>	
Oral Hypoglycaemic Agents				
GLIBENCLAMIDE				
* Tab 5 mg	7 50	100	🗸 Daonil	
C C		100	- Davini	
GLICLAZIDE	00.10	500		
* Tab 80 mg		500	✓ <u>Glizide</u>	
GLIPIZIDE			<b>6</b> • • • • • •	
* Tab 5 mg	6.86	100	<ul> <li>Minidiab</li> </ul>	
METFORMIN HYDROCHLORIDE				
* Tab immediate-release 500 mg		1,000	<ul> <li>Metformin Viatris</li> </ul>	
* Tab immediate-release 850 mg	11.28	500	<ul> <li>Metformin Viatris</li> </ul>	
PIOGLITAZONE				
* Tab 15 mg	6.15	90	<ul> <li>Vexazone</li> </ul>	
* Tab 30 mg		90	<ul> <li>Vexazone</li> </ul>	
* Tab 45 mg		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	FullyBrand orSubsidisedGeneric✓Manufacturer	
VILDAGLIPTIN				
Tab 50 mg	35.00	60	<ul> <li>Galvus</li> </ul>	
VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE				
Tab 50 mg with 1,000 mg metformin hydrochloride	35.00	60	<ul> <li>Galvumet</li> </ul>	
Tab 50 mg with 850 mg metformin hydrochloride	35.00	60	<ul> <li>Galvumet</li> </ul>	

**GLP-1 Agonists** 

DULAGLUTIDE - Special Authority see SA2492 below - Retail pharmacy

#### ⇒SA2492 Special Authority for Subsidy

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

All of the following:

- 1 Patient has type 2 diabetes; and
- 2 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of all of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin; and
- 3 Any of the following:
  - 3.1 Patient is Māori or any Pacific ethnicity\*; or
  - 3.2 Patient has pre-existing cardiovascular disease or risk equivalent (see note a)\*; or
  - 3.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator\*; or
  - 3.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult\*; or
  - 3.5 Patient has diabetic kidney disease (see note b)\*.

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 identified.
- c) Funded GLP-1a treatment is not to be given in combination with (empagliflozin /empagliflozin with metformin hydrochloride) unless receiving (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

LIRAGLUTIDE - Special Authority see SA2440 on the next page - Retail pharmacy

- a) Maximum of 9 inj per prescription
- b)
- a) Note: Not to be given in combination with another funded GLP-1 agonist or empagliflozin / empagliflozin with metformin hydrochloride unless receiving empagliflozin / empagliflozin with metformin hydrochloride for the treatment of heart failure.

b) Maximum of 1 pack of 3 (6 mg per ml. 3 ml) prefilled pens will be funded per month.

	Inj 6 mg per ml, 3 ml pr	refilled pen		3	<ul> <li>Victoza</li> </ul>
--	--------------------------	--------------	--	---	-----------------------------

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

#### ⇒SA2440 Special Authority for Subsidy

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

All of the following:

- 1 Patient has type 2 diabetes; and
- 2 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of all of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin; and
- 3 Any of the following:
  - 3.1 Patient is Māori or any Pacific ethnicity\*; or
  - 3.2 Patient has pre-existing cardiovascular disease or risk equivalent (see note a)\*; or
  - 3.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator\*; or
  - 3.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult\*; or
  - 3.5 Patient has diabetic kidney disease (see note b)\*.
- 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 identified.
  - c) Funded GLP-1a treatment is not to be given in combination with (empagliflozin /empagliflozin with metformin hydrochloride) unless receiving (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

### SGLT2 Inhibitors

#### ⇒SA2408 Special Authority for Subsidy

**Initial application** — (heart failure reduced ejection fraction) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 Patient has heart failure; and
- 2 Patient is in NYHA functional class II or III or IV; and
- 3 Either:
  - 3.1 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; or
  - 3.2 An ECHO is not reasonably practicable, and in the opinion of the treating practitioner the patient would benefit from treatment; and
- 4 Patient is receiving concomitant optimal standard funded chronic heart failure treatment.

Initial application — (Type 2 Diabetes) 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

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist. \*Three months or six months, as applicable, dispensed all-at-once

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

continued...

- 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.
- c) Funded [empagliflozin / empagliflozin with metformin hydrochloride] treatment is not to be given in combination with a funded GLP-1 unless receiving (empagliflozin / empagliflozin with metformin hydrochloride] for the treatment of heart failure.

EMPAGLIFLOZIN - Spe	cial Authority see SA2408 on	the previous page – Retail pharmac	y
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* Tab 10 mg		30	<ul> <li>Jardiance</li> </ul>
* Tab 25 mg	58.56	30	<ul> <li>Jardiance</li> </ul>
EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE - S	Special Authority se	e SA2408 o	n the previous page – Retail
pharmacy			
* Tab 5 mg with 1,000 mg metformin hydrochloride		60	<ul> <li>Jardiamet</li> </ul>
* Tab 5 mg with 500 mg metformin hydrochloride		60	<ul> <li>Jardiamet</li> </ul>
* Tab 12.5 mg with 1,000 mg metformin hydrochloride		60	<ul> <li>Jardiamet</li> </ul>
* 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.

•••

- KetoSens

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Dual Blood Glucose and Blood Ketone Testing				
<ul> <li>DUAL BLOOD GLUCOSE AND BLOOD KETONE DIAGNOSTIC</li> <li>a) Maximum of 1 pack per prescription</li> <li>b) Up to 1 pack available on a PSO</li> <li>c) A dual blood glucose and blood ketone diagnostic test mathematical diabetes; or</li> <li>2) permanent neonatal diabetes; or</li> <li>3) undergone a pancreatectomy; or</li> <li>4) cystic fibrosis-related diabetes; or</li> <li>5) metabolic disease or epilepsy under the care of a p.</li> <li>The prescription must be endorsed accordingly. Only 1 r the avoidance of doubt patients who have previously reconfunded CareSens meter.</li> <li>Meter with 50 lancets, a lancing device and 10 blood glucose diagnostic test strips</li> </ul>	eter is subsidised for aediatrician, neurolog neter per patient will pived a funded meter,	a pati jist or be su	metabolic sp bsidised (no r than CareS	: pecialist. repeat prescriptions). For
		101	. 0	
Blood Glucose Testing				
<ul> <li>BLOOD GLUCOSE DIAGNOSTIC TEST METER – Subsidy by et a) Maximum of 1 pack per prescription</li> <li>b) Up to 1 pack available on a PSO</li> <li>c) A diagnostic blood glucose test meter is subsidised for a <ol> <li>is receiving insulin or sulphonylurea therapy; or</li> <li>is pregnant with diabetes; or</li> <li>is on home TPN at risk of hypoglycaemia or hyperg</li> <li>has a genetic or an acquired disorder of glucose ho syndrome.</li> </ol> </li> <li>The prescription must be endorsed accordingly. Only on prescriptions). Patients already using the CareSens N Prescription must be endorsed accordingly. Only on prescriptions). Patients already using the CareSens N Prescription a pancreatectomy; or</li> <li>type 1 diabetes; or</li> <li>undergone a pancreatectomy; or</li> <li>cystic fibrosis-related diabetes.</li> <li>For the avoidance of doubt patients who have previously funded CareSens meter.</li> </ul>	patient who: lycaemia; or meostasis, excluding e CareSens meter pe OP meter and CareS received a funded most	er pati ens N	ent will be su I meter are n other than Ca	ubsidised (no repeat ot eligible for a new
Note: Only 1 meter available per PSO	20.00		-	areSens N Premier

	Subsidy (Manufacturer's Price) \$	Subs Per	Fully sidised	Brand or Generic Manufacturer
.OOD GLUCOSE DIAGNOSTIC TEST STRIP - Up to 50 test	t available on a PSO			
The number of test strips available on a prescription is restr	icted to 50 unless:			
1) Prescribed for a patient on insulin or a sulphonylurea				
prescription as endorsed where there exists a record				
<ol> <li>Prescribed on the same prescription as insulin or a su endorsed; or</li> </ol>	Iphonylurea in which c	ase the pr	escripti	on is deemed to be
<ol><li>Prescribed for a pregnant woman with diabetes and e</li></ol>				
<ol><li>Prescribed for a patient on home TPN at risk of hypog</li></ol>				
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 acc	cordingly.			
Test strips		test OP	-	areSens N areSens PRO
OOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)				
The number of test strips available on a prescription is restr	icted to 50 unless:			
<ol> <li>Prescribed for a patient on insulin or a sulphonylureal prescription as endorsed where there exists a record of</li> </ol>				
2) Prescribed on the same prescription as insulin or a su	Iphonylurea in which c	ase the pr	escripti	on is deemed to be
endorsed; or				
3) Prescribed for a pregnant woman with diabetes and e				
<ol> <li>Prescribed for a pregnant woman with diabetes and e</li> <li>Prescribed for a patient on home TPN at risk of hypog</li> </ol>	lycaemia or hyperglyc	aemia and		
3) Prescribed for a pregnant woman with diabetes and e	lycaemia or hyperglyca	aemia and		

## Insulin Syringes and Needles

INSULIN PEN NEEDLES - Maximum of 200 deviner prescription

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 liraglutide or when prescribed for a patient and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or liraglutide.

1110			
*	29 g × 12.7 mm	 100	B-D Micro-Fine
*	31 g × 5 mm	 100	B-D Micro-Fine
		 100	<ul> <li>Berpu</li> </ul>
		 100	B-D Micro-Fine
		 100	B-D Micro-Fine
	U U		

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
INS	ULIN SYRINGES, DISPOSABLE WITH ATTACHED NEEDLE	– Maximum of 200	dev p	per prescrip	tion
*	Syringe 0.3 ml with 29 g × 12.7 mm needle	13.56	100	<ul> <li>I</li> </ul>	B-D Ultra Fine
		1.36	10		
		(1.99)		E	B-D Ultra Fine
*	Syringe 0.3 ml with 31 g × 8 mm needle		100	✓ I	B-D Ultra Fine II
		1.30	10		
		(1.99)		E	B-D Ultra Fine II
*	Syringe 0.5 ml with 29 g × 12.7 mm needle		100	✓ I	B-D Ultra Fine
		1.36	10		
		(1.99)		E	B-D Ultra Fine
*	Syringe 0.5 ml with 31 g × 8 mm needle		100	✓ I	B-D Ultra Fine II
		1.36	10		
		(1.99)		E	B-D Ultra Fine II
*	Syringe 1 ml with 29 g × 12.7 mm needle		100	✓ I	B-D Ultra Fine
		1.36	10		
		(1.99)		E	B-D Ultra Fine
*	Syringe 1 ml with 31 g × 8 mm needle	13.56	100	✓	B-D Ultra Fine II
		1.36	10		
		(1.99)		E	B-D Ultra Fine II

### **Insulin Pumps**

INSULIN PUMP WITH ALGORITHM - Special Authority see SA2367 below - Retail pharmacy

		riotal priaritacy	
<ul><li>a) Maximum of 1 dev per prescription</li><li>b) Only on a prescription</li></ul>			
c) Maximum of 1 insulin pump per patient each fou	r year period.		
Min basal rate 0.02 U/h		1	<ul> <li>mylife YpsoPump with CamAPS FX</li> </ul>
Min basal rate 0.1 U/h	7,653.00	1	<ul> <li>Tandem t:slim X2 with Basal-IQ</li> </ul>
			<ul> <li>Tandem t:slim</li> <li>X2 with Control-IQ</li> </ul>

#### ➡SA2367 Special Authority for Subsidy

**Initial application** — (type 1 diabetes) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 The patient has type 1 diabetes; or
  - 1.2 The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist as likely to benefit; or
  - 1.3 The patient has Type 3c diabetes considered by the treating endocrinologist as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis); or
  - 1.4 The patient has atypical inherited forms of diabetes; and
- 2 Patient has been evaluated by a diabetes multidisciplinary team for their suitability for insulin pump therapy; and
- 3 In the opinion of the treating relevant practitioner the patient would benefit from an Automated Insulin Delivery (AID) system.

Renewal — (type 1 diabetes) from any relevant practitioner. Approvals valid for 6 months where the patient is continuing to derive benefit according to the treatment plan agreed at induction.

	Subsidy (Manufacturer's Price \$	) Sul Per	Fully osidised	Brand or Generic Manufacturer
Insulin Pump Consumables				
SA2380 Special Authority for Subsidy				
nitial application — (type 1 diabetes) from any relevant pra	ctitioner. Approvals va	alid for 2 y	ears for	applications meeting the
ollowing criteria:		-		
Il of the following:				
1 Any of the following:				
1.1 The patient has type 1 diabetes; or				
1.2 The patient has permanent neonatal diabetes or		iabetes su	btypes w	vith insulin deficiency,
considered by the treating endocrinologist as like 1.3 The patient has Type 3c diabetes considered by		logist og l	ikolu to h	onofit (Tuno 20 diabotoo
includes insulin deficiency due to pancreatector				
1.4 The patient has atypical inherited forms of diabe		boondary	io oyollo	
2 Patient has been evaluated by a diabetes multidisciplina		bility for ir	isulin pui	mp therapy; and
3 In the opinion of the treating relevant practitioner the pa				
system.				
Renewal — (type 1 diabetes) from any relevant practitioner.		years whe	re the pa	tient is continuing to
erive benefit according to the treatment plan agreed at induct				
NSULIN PUMP CARTRIDGE – Special Authority see SA2380	) above – Retail pharn	nacy		
a) Maximum of 50 cart per prescription				
<ul><li>b) Only on a prescription</li><li>c) Maximum of 190 cartridges will be funded per year.</li></ul>				
<ul> <li>Cartridge 300 u, t:lock × 10</li> </ul>	86.00	10 OP	🗸 т	andem Cartridge
NSULIN PUMP INFUSION SET (STEEL CANNULA) – Specia				5
a) Maximum of 5 set per prescription			riciali p	паппасу
b) Only on a prescription				
c) Maximum of 19 infusion sets will be funded per year.				
₭ 6 mm steel needle; 60 cm tubing × 10		1 OP	🗸 N	liniMed Sure-T
				MMT-864A
6 mm steel needle; 80 cm tubing × 10		1 OP	N	liniMed Sure-T
				MMT-866A
₭ 8 mm steel needle; 60 cm tubing × 10		1 OP	✓ N	liniMed Sure-T
₭ 8 mm steel needle; 80 cm tubing × 10	130.00	1 OP	<b>/</b> N	MMT-874A IiniMed Sure-T
		I UF	• N	MMT-876A
MiniMed Sure-T MMT-864A 6 mm steel needle; 60 cm tubing	× 10 to be delisted 1 (	October 20	)26)	
MiniMed Sure-T MMT-866A 6 mm steel needle; 80 cm tubing				
NiniMed Sure-T MMT-874A 8 mm steel needle; 60 cm tubing				

(MiniMed Sure-T MMT-876A 8 mm steel needle; 80 cm tubing × 10 to be delisted 1 October 2026)

		Subsidy (Manufacturer's F \$	Price) Per	Fully Subsidised	Brand or Generic Manufacturer
	ULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT	INSERTION) -	- Special A	Authority see	SA2380 on the previous
pag	e – Retail pharmacy a) Maximum of 5 sets per prescription				
	b) Only on a prescription				
	<ul><li>c) Maximum of 19 infusion sets will be funded per year.</li></ul>				
*	5.5 mm steel cannula; straight insertion; 45 cm line × 10 with				
	10 needles	136.00	1 OF	° ∕n	nylife Orbit micro
*	5.5 mm steel needle; straight insertion; 60 cm line × 10 with 10 needles	136.00	1 OF	, <b>√</b> n	nylife Orbit micro
*	5.5 mm steel needle; straight insertion; 80 cm line × 10 with 10 needles	136.00	1 OF	, <b>√</b> u	nylife Orbit micro
*	8.5 mm steel needle; straight insertion; 60 cm line $\times$ 10 with				
	10 needles	136.00	1 OF	∕ <b>√</b> n	nylife Orbit micro
*	8.5 mm steel needle; straight insertion; 80 cm line $\times$ 10 with				
	10 needles	136.00	1 OF	° ∕n	nylife Orbit micro
*	6 mm steel cannula; straight insertion; 80 cm line × 10 with 10 needles	182.00	1 OF	, <b>√</b> ⊥	ruSteel
*	8 mm steel cannula; straight insertion; 80 cm line × 10 with				
	10 needles	182.00	1 OF	° <b>√</b> ⊺	ruSteel
*	6 mm steel cannula; straight insertion; 60 cm line × 10 with 10 needles	182.00	1 OF	, <b>√</b> ⊺	ruSteel
*	8 mm steel cannula; straight insertion; 60 cm line × 10 with				
	10 needles	182.00	1 OF	у √т	ruSteel

		Subsidy (Manufacturer's Price)		Fully Subsidised	
		(Manufacturer's Price) \$	Per	Subsidised	Manufacturer
N	SULIN PUMP INFUSION SET (TEFLON CANNULA) – Specia	al Authority see SA23	30 on	page 18 -	- Retail pharmacy
	a) Maximum of 5 set per prescription	-			
	b) Only on a prescription				
	c) Maximum of 19 infusion sets will be funded per year.				
*	13 mm teflon needle, 60 cm tubing × 10		1 OP		MiniMed Silhouette MMT-381A
*	17 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	1	MiniMed Silhouette MMT-377A
*	17 mm teflon needle, 60 cm tubing x 10	130.00	1 OP	1	MiniMed Silhouette MMT-378A
*	6 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	1	MiniMed Quick-Set MMT-398A
*	6 mm teflon needle, 45 cm blue tubing $\times$ 10	130.00	1 OP	1	MiniMed Mio MMT-941A
*	6 mm teflon needle, 45 cm pink tubing × 10	130.00	1 OP	1	MiniMed Mio MMT-921A
*	6 mm teflon needle, 60 cm blue tubing × 10	130.00	1 OP	1	MiniMed Mio MMT-943A
*	6 mm teflon needle, 60 cm pink tubing × 10	130.00	1 OP	1	MiniMed Mio MMT-923A
*	6 mm teflon needle, 60 cm tubing × 10	130.00	1 OP	1	MiniMed Quick-Set MMT-399A
*	6 mm teflon needle, 80 cm blue tubing	130.00	1 OP	1	MiniMed Mio MMT-945A
*	6 mm teflon needle, 80 cm clear tubing × 10	130.00	1 OP	1	MiniMed Mio MMT-965A
*	6 mm teflon needle, 80 cm pink tubing × 10	130.00	1 OP	1	MiniMed Mio MMT-925A
*	9 mm teflon needle, 110 cm tubing × 10	130.00	1 OP	1	MiniMed Quick-Set MMT-396A
*	9 mm teflon needle, 60 cm tubing × 10	130.00	1 OP	1	MiniMed Quick-Set MMT-397A
*	9 mm teflon needle, 80 cm clear tubing × 10	130.00	1 OP	1	MiniMed Mio MMT-975A

(MiniMed Silhouette MMT-381A 13 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Silhouette MMT-377A 17 mm teflon needle, 110 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Silhouette MMT-378A 17 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-398A 6 mm teflon needle, 10 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-941A 6 mm teflon needle, 45 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-921A 6 mm teflon needle, 45 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-921A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-923A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-923A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-923A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-925A 6 mm teflon needle, 80 cm clear tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-925A 6 mm teflon needle, 80 cm clear tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-925A 6 mm teflon needle, 80 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-925A 6 mm teflon needle, 80 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-925A 6 mm teflon needle, 80 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-396A 9 mm teflon needle, 10 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-397A 9 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-397A 9 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026)

	Subsidy (Manufacturer's Pric		Fully bsidised	Brand or Generic
	\$	Per	1	Manufacturer
INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE	INSERTION WITH I	NSERTIO	N DEVIC	E) – Special Authority see
SA2380 on page 18 – Retail pharmacy				
<ul> <li>a) Maximum of 5 sets per prescription</li> <li>b) Only on a propagintian</li> </ul>				
<ul><li>b) Only on a prescription</li><li>c) Maximum of 19 infusion sets will be funded per year.</li></ul>				
<ul> <li>* 13 mm teflon cannula; angle insertion; insertion device; 110</li> </ul>	) om			
line × 10 with 10 needles		1 OP	🗸 🗸	utoSoft 30
* 13 mm teflon cannula; angle insertion; insertion device; 60 line × 10 with 10 needles		1 OP	✓ A	utoSoft 30
INSULIN PUMP INFUSION SET (TEFLON CANNULA, FLEXIB	I F INSERTION WIT	H INSERT		/ICF) – Special Authority
see SA2380 on page 18 – Retail pharmacy		IIIIIO EIII		
a) Maximum of 5 set per prescription				
b) Only on a prescription				
c) Maximum of 19 infusion sets will be funded per year.				
* 6 mm teflon cannula; flexible insertion; insertion device; 46				
line × 10 with 10 needles		1 OP	🗸 n	nylife Inset soft
* 6 mm teflon cannula; flexible insertion; insertion device; 60				
line with integrated inserter × 10 with 10 needles		1 OP	✓ n	nylife Inset soft
* 6 mm teflon cannula; flexible insertion; insertion device; 80		4.00		
line × 10 with 10 needles		1 OP	✓ n	nylife Inset soft
* 9 mm teflon cannula; flexible insertion; insertion device; 60		1.00		ulife lucet ceft
line × 10 with 10 needles		1 OP	✓ n	nylife Inset soft
# 9 mm teflon cannula; flexible insertion; insertion device; 80 line × 10 with 10 needles		1 OP		wife inect coff
		-		nylife Inset soft
INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIG	HI INSERTION WI	I H INSER	TION DE	VICE) – Special Authority
see SA2380 on page 18 – Retail pharmacy				
<ul><li>a) Maximum of 5 sets per prescription</li><li>b) Only on a prescription</li></ul>				
c) Maximum of 19 infusion sets will be funded per year.				
* 6 mm teflon cannula; straight insertion; insertion device;				
110 cm line × 10 with 10 needles		1 OP	🗸 A	utoSoft 90
* 6 mm teflon cannula; straight insertion; insertion device; 60		-		
line × 10 with 10 needles		1 OP	🗸 A	utoSoft 90
* 9 mm teflon cannula; straight insertion; insertion device;				
110 cm line × 10 with 10 needles		1 OP	🗸 🗸	utoSoft 90
* 9 mm teflon cannula; straight insertion; insertion device; 60	cm			
line × 10 with 10 needles		1 OP	🗸 🗸	utoSoft 90
INSULIN PUMP INFUSION SET (TEFLON CANNULA, VARIAE	BLE INSERTION) -	Special Au	thoritv se	e SA2380 on page 18 -
Retail pharmacy	- /		.,	in the second
a) Maximum of 5 set per prescription				
b) Only on a prescription				
c) Maximum of 19 infusion sets will be funded per year.				
* 13 mm teflon cannula; variable insertion; 60 cm line × 10 w			-	
10 needles		1 OP	• V	ariSoft

	Subsidy (Manufacturer's Price) \$	S Per	Fully Subsidised	Brand or Generic Manufacturer
NSULIN PUMP RESERVOIR - Special Authority see SA2380 or	page 18 – Retail p	harmac	ÿ	
<ul> <li>a) Maximum of 90 cart per prescription</li> <li>b) Only on a prescription</li> <li>c) Maximum of 360 reservoirs will be funded per year.</li> </ul>				
✤ 10 × 1.6 ml glass reservoir for YpsoPump	50.00	10 OP	1	mylife YpsoPump Reservoir
10 × luer lock conversion cartridges 1.8 ml for paradigm pump	s50.00	10 OP	1	ADR Cartridge 1.8
Cartridge for 7 series pump; 3.0 ml × 10	50.00	10 OP	1	MiniMed 3.0 Reservoir MMT-332A
ADR Cartridge 1.8 10 × luer lock conversion cartridges 1.8 ml for MiniMed 3.0 Reservoir MMT-332A Cartridge for 7 series pump; 3				,

### **Continuous Glucose Monitor**

CC	NTINUOUS GLUCOSE MONITOR (INTEROPERABLE) - Special Authority se	ee SA2371 be	elow – Retail pharmacy
	Only on a prescription		
*	Sensor (9) and transmitter (Dexcom G6) – Maximum of 1 dev		
	per prescription	1 OP	<ul> <li>Dexcom G6</li> </ul>
	Maximum of 5 dev will be funded per year.		
*	Sensor (Dexcom G7) – Maximum of 9 dev per prescription	1	<ul> <li>Dexcom G7</li> </ul>
*	Sensor (Freestyle Libre 3 Plus) – Maximum of 6 dev per		
~	prescription	1	<ul> <li>Freestyle Libre 3 Plus</li> </ul>

Maximum of 28 dev will be funded per year.

#### ⇒SA2371 Special Authority for Subsidy

**Initial application — (type 1 diabetes)** 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 type 1 diabetes; or
  - 1.2 The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit; or
  - 1.3 The patient has Type 3c diabetes considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis); or
  - 1.4 The patient has atypical inherited forms of diabetes; and
- 2 In the opinion of the treating relevant practitioner the patient would benefit from an Automated Insulin Delivery (AID) system.

Renewal — (type 1 diabetes) from any relevant practitioner. Approvals valid for 2 years where the patient is continuing to derive benefit according to the treatment plan agreed at induction.

	Subsidy (Manufacturer's Price)	Subs Per	Fully idised	Brand or Generic Manufacturer
	\$			
CONTINUOUS GLUCOSE MONITOR (STANDALONE) - Special	Authority see SA23	70 below	- Retail	pharmacy
Only on a prescription				
<ul> <li>Sensor (Dexcom ONE+) – Maximum of 9 dev per prescription Maximum of 40 dev will be funded per year.</li> </ul>	81.00	1	✓ D	excom ONE+
* Sensor (Freestyle Libre 2 Plus) – Maximum of 6 dev per				
prescription	99.46	1	✔ F	reestyle Libre 2 Plus
Maximum of 28 dev will be funded per year.				
Sensor (Freestyle Libre 2) – Maximum of 7 dev per prescription Maximum of 29 dev will be funded per year. (Freestyle Libre 2) to be delived 1 May.		1	✔ F	reestyle Libre 2

(Freestyle Libre 2 Sensor (Freestyle Libre 2) to be delisted 1 May 2026)

#### ⇒SA2370 Special Authority for Subsidy

**Initial application** — (type 1 diabetes) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 The patient has type 1 diabetes; or
- 2 The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit; or
- 3 The patient has Type 3c diabetes considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis); or
- 4 The patient has atypical inherited forms of diabetes.

Renewal — (type 1 diabetes) from any relevant practitioner. Approvals valid for 2 years where the patient is continuing to derive benefit according to the treatment plan agreed at induction.

### **Digestives Including Enzymes**

#### PANCREATIC ENZYME

Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase			
10,000 Ph Eur U, total protease 600 Ph Eur U)	34.93	100	<ul> <li>Creon 10000</li> </ul>
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	<ul> <li>Creon 25000</li> </ul>
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	<ul> <li>Creon Micro</li> </ul>
URSODEOXYCHOLIC ACID - Special Authority see SA2448 below	<ul> <li>Retail pha</li> </ul>	irmacy	
Cap 250 mg	33.95	100	<ul> <li>Ursosan</li> </ul>

#### ⇒SA2448 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

continued...

AThree 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	I Generic	
\$	Per 🗸	Manufacturer	

continued...

3 Treatment with ursodeoxycholic acid may prevent hospital admission or reduce duration of stay.

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

Both:

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

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

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

Both:

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

**Initial application — (prevention of sinusoidal obstruction syndrome)** from any relevant practitioner. Approvals valid without further renewal unless notified where the individual has leukaemia/lymphoma and requires prophylaxis for medications/therapies with a high risk of sinusoidal obstruction syndrome.

### Laxatives

### **Bulk-forming Agents**

ISPAGHULA (PSYLLIUM) HUSK – Only on a prescription * Powder for oral soln	500 g OP	✓ Konsyl-D
Faecal Softeners		
DOCUSATE SODIUM – Only on a prescription		
* Tab 50 mg	100	<ul> <li>Coloxyl</li> </ul>
* Tab 120 mg4.98	100	✓ Coloxyl
DOCUSATE SODIUM WITH SENNOSIDES		
Tab 50 mg with sennosides 8 mg	200	<ul> <li>Laxsol</li> </ul>
POLOXAMER – Only on a prescription		
Not funded for use in the ear.		
* Oral drops 10%4.17	30 ml OP	✓ <u>Coloxyl</u>

	Subsidy (Manufacturer's Pric		Fully Brand or dised Generic
	\$	Per	<ul> <li>Manufacturer</li> </ul>
Opioid Receptor Antagonists - Peripheral			
METHYLNALTREXONE BROMIDE – Special Authority see S/ Inj 12 mg per 0.6 ml vial		pharmacy 1 7	<ul> <li>✓ Relistor</li> <li>✓ Relistor</li> </ul>
SA1691 Special Authority for Subsidy nitial application — (Opioid induced constipation) from an inless notified for applications meeting the following criteria: Both:	y relevant practitione	r. Approvals	valid without further renewal
<ol> <li>The patient is receiving palliative care; and</li> <li>Either:</li> </ol>			
<ul><li>2.1 Oral and rectal treatments for opioid induced cor</li><li>2.2 Oral and rectal treatments for opioid induced cor</li></ul>			d.
Osmotic Laxatives			
GLYCEROL	10.39	20	<ul> <li>Lax-suppositories Glycerol</li> </ul>
.ACTULOSE – Only on a prescription ₭ Oral liq 10 g per 15 ml	3.61	500 ml	<ul> <li>Laevolac</li> </ul>
MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM I		SODIUM CH	ILORIDE
Powder for oral soln 13.125 g with potassium chloride 46.6 sodium bicarbonate 178.5 mg and sodium chloride 350		30	<ul> <li>✓ APO Health Macrogol S29</li> <li>✓ Molaxole</li> </ul>
SODIUM ACID PHOSPHATE – Only on a prescription Enema 16% with sodium phosphate 8%	2.50	1	✓ Fleet Phosphate Enema
SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETA	• •	cription	
Enema 90 mg with sodium lauryl sulphoacetate 9 mg per r 5 ml	,	50	✓ Micolette
Stimulant Laxatives			
BISACODYL – Only on a prescription ★ Tab 5 mg ★ Suppos 10 mg		200 10	<ul> <li>Bisacodyl Viatris</li> <li>Lax-Suppositories</li> </ul>
SENNA – Only on a prescription ₭ Tab, standardised	(9.38)	100	Senokot
	0.43 (2.06)	20	Senokot
SODIUM PICOSULFATE – Special Authority see SA2053 on t Oral soln 7.5 mg per ml		l pharmacy 30 ml OP	<ul> <li>Duicolax SP Drop</li> </ul>

Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic
(Manulacturer 5 T Hee) \$	Per		Manufacturer

#### ⇒SA2053 Special Authority for Subsidy

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

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

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

### **Metabolic Disorder Agents**

ALGLUCOSIDASE ALFA - Special Authority see SA1986 below - Retail pharmacy

Inj 50 mg vial .....1,142.60

✓ Myozyme

1

#### ➡SA1986 Special Authority for Subsidy

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

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

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

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

ARGININE - Special Authority see SA2042 on the next page - Retail pharmacy

Tab 1,000 mg	CBS	90	<ul> <li>Clinicians</li> </ul>
Cap 500 mg		50	<ul> <li>Solgar</li> </ul>
Powder		400 g	<ul> <li>Biomed</li> </ul>

	Subsidy (Manufacturer's Price) \$	F Subsid Per	Fully ised ✓	Brand or Generic Manufacturer
<ul> <li>⇒SA2042 Special Authority for Subsidy</li> <li>Initial application only from a metabolic physician. Approvals metabolism that may respond to arginine supplementation.</li> <li>Renewal only from a metabolic physician. Approvals valid for 2 Both:         <ol> <li>The patient has a confirmed diagnosis of an inborn error</li> </ol> </li> </ul>	4 months for applicatio	ons meeting	the fol	lowing criteria:
2 The treatment remains appropriate and the patient is be			yinine :	supplementation, and
BETAINE – Special Authority see SA1987 below – Retail pharr Powder for oral soln		30 g OP	✔ Cy	stadane
<ul> <li>SA1987 Special Authority for Subsidy</li> <li>Initial application only from a metabolic physician. Approvals</li> <li>All of the following:         <ol> <li>The patient has a confirmed diagnosis of homocystinuria</li> <li>Any of the following:                 <ol> <li>A cystathionine beta-synthase (CBS) deficiency;</li> <li>A formethylene-tetrahydrofolate reductase (MT 2.3 A disorder of intracellular cobalamin metabolism;</li> <li>An appropriate homocysteine level has not been achieved</li> </ol> </li> </ol> </li> </ul>	; and or 'HFR) deficiency; or and			
Renewal only from a metabolic physician. Approvals valid for 1 patient is benefiting from treatment.				
COENZYME Q10 – Special Authority see SA2039 below – Ret Cap 120 mg Cap 160 mg SA2039 Special Authority for Subsidy	CBS	30 60	✔ So ✔ Go	lgar I Healthy
<b>Initial application</b> only from a metabolic physician. Approvals metabolism that may respond to coenzyme Q10 supplementatic <b>Renewal</b> only from a metabolic physician. Approvals valid for 2	on.			
Both:         1         The patient has a confirmed diagnosis of an inborn error and         2         The treatment remains appropriate and the patient is being a second seco			enzym	e Q10 supplementation;
GALSULFASE – Special Authority see SA1988 below – Retail Inj 1 mg per ml, 5 ml vial		1	🗸 Na	glazyme
■ SA1988 Special Authority for Subsidy Initial application only from a metabolic physician. Approvals Both:		applications	meeti	ng the following criteria:
<ol> <li>The patient has been diagnosed with mucopolysaccharid</li> <li>Either:</li> <li>2.1 Diagnosis confirmed by demonstration of N-acety enzyme activity assay in leukocytes or skin fibrob</li> <li>2.2 Detection of two disease causing mutations and p VI.</li> </ol>	rl-galactosamine-4-sulf lasts; or			

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

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist. \*Three months or six months, as applicable, dispensed all-at-once

	<b>a</b>			
	Subsidy (Manufacturer's Price \$	e) Su Per	Fully ubsidised	Brand or Generic Manufacturer
continued				
<ol> <li>Patient has not had severe infusion-related adverse read and/or adjustment of infusion rates; and</li> <li>Patient has not developed another life threatening or sev influenced by Enzyme Replacement Therapy (ERT); and</li> <li>Patient has not developed another medical condition that</li> </ol>	rere disease where th	ne long te	rm progno	osis is unlikely to be
ERT. IDURSULFASE – Special Authority see SA1623 below – Retail	nharmacy			
Inj 2 mg per ml, 3 ml vial		1	✓ E	laprase
<ul> <li>⇒SA1623 Special Authority for Subsidy</li> <li>Initial application only from a metabolic physician. Approvals and the following:</li> <li>1 The patient has been diagnosed with Hunter Syndrome (</li> </ul>				ing the following criteria:
<ol> <li>2 Either:</li> <li>2.1 Diagnosis confirmed by demonstration of idurona assay in cultured skin fibroblasts; or</li> <li>2.2 Detection of a disease causing mutation in the idu</li> </ol>		-	ite blood	cells by either enzyme
<ol> <li>Patient is going to proceed with a haematopoietic stem c idursulfase would be bridging treatment to transplant; an</li> <li>Patient has not required long-term invasive ventilation for</li> </ol>	ell transplant (HSCT d	) within th		
<ul> <li>(ERT); and</li> <li>Idursulfase to be administered for a total of 24 weeks (ed greater than 0.5 mg/kg every week.</li> </ul>				
LARONIDASE – Special Authority see SA1695 below – Retail p Inj 100 U per ml, 5 ml vial		1	✓ A	Aldurazyme
► SA1695 Special Authority for Subsidy Initial application only from a metabolic physician. Approvals All of the following:	valid for 24 weeks fo	r applicati	ons meet	ing the following criteria:
<ol> <li>The patient has been diagnosed with Hurler Syndrome ( 2 Either:</li> </ol>	mucopolysacchardos	is I-H); ar	nd	
2.1 Diagnosis confirmed by demonstration of alpha-L assay in cultured skin fibroblasts; or		-		
<ol> <li>Detection of two disease causing mutations in the to have Hurler syndrome; and</li> </ol>	aipna-L-iduronidase	e gene an	d patient	has a sidling who is known
3 Patient is going to proceed with a haematopoietic stem c laronidase would be bridging treatment to transplant; and	ł			
<ol> <li>Patient has not required long-term invasive ventilation fo (ERT); and</li> <li>Laronidase to be administered for a total of 24 weeks (ed)</li> </ol>				
than 100 units/kg every week.				
LEVOCARNITINE – Special Authority see SA2040 on the next Tab 500 mg Cap 250 mg Cap 500 mg	CBS	30 30 60	√ S √ E	Solgar Solgar Balance
Oral liq 1 g per 10 ml	CBS	300 118 ml	✓ (	Aetabolics Carnitor 529 Iovitium Sugar Free 529
Oral liq 500 mg per 10 ml	CBS	300 ml	✓ E	Balance
(Carnitor \$23) Oral liq 1 g per 10 ml to be delisted 1 October 20			_	

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

#### ⇒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. BIBOELAVIN - Special Authority see SA2041 below. Betail phormaou

Tab 100 mg		100	<ul> <li>Country Life</li> <li>Puritan's Pride</li> <li>Vitamin</li> <li>B-2 100 mg \$29</li> </ul>
Cap 100 mg	CBS	100	<ul> <li>Solgar</li> </ul>

#### ⇒SA2041 Special Authority for Subsidy

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

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

Both:

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

SAPROPTERIN DIHYDROCHLORIDE – Special Authority see SA1989 below – Retail pharmacy

Tab soluble 100 mg...... 1,452.70 30 OP 🗸 Kuvan

#### ➡SA1989 Special Authority for Subsidy

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

- 1 Patient has phenylketonuria (PKU) and is pregnant or actively planning to become pregnant; and
- 2 Treatment with sapropterin is required to support management of PKU during pregnancy; and
- 3 Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg; and
- 4 Sapropterin to be used alone or in combination with PKU dietary management; and
- 5 Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery.

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

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

All of the following:

1 Either:

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

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist. \*Three months or six months, as applicable, dispensed all-at-once

	Subsidy (Manufacturer's Price \$	e) Subs Per	Fully sidised	
continued				
<ol> <li>Sapropterin to be used alone or in combination with PKU</li> <li>Total treatment duration with sapropterin will not exceed becoming pregnant) and treatment will be stopped after of</li> </ol>	22 months for each	,	incluc	les time for planning and
SODIUM BENZOATE – Special Authority see SA1599 below – Soln 100 mg per ml	• •	100 ml	1	Amzoate S29
SA1599 Special Authority for Subsidy Initial application only from a metabolic physician. Approvals v cycle disorder.	valid for 12 months w	where the pa	atient I	has a diagnosis of a urea
Renewal only from a metabolic physician. Approvals valid for 1 patient is benefiting from treatment.	2 months where the	treatment re	emain	s appropriate and the
SODIUM PHENYLBUTYRATE – Special Authority see SA1990 Grans 483 mg per g		macy 174 g OP	1	Pheburane
SA1990 Special Authority for Subsidy Initial application only from a metabolic physician. Approvals v cycle disorder involving a deficiency of carbamylphosphate synt synthetase.				
<b>Renewal</b> only from a metabolic physician. Approvals valid for 1 patient is benefiting from treatment.	2 months where the	treatment re	emain	s appropriate and the
TAURINE – Special Authority see SA2043 below – Retail pharr Cap 500 mg Cap 1,000 mg Powder	CBS	50 90 300 g	✓	Solgar Life Extension Life Extension
<ul> <li>SA2043 Special Authority for Subsidy</li> <li>Initial application only from a metabolic physician. Approvals on mitochondrial disorder that may respond taurine supplementation</li> <li>Renewal only from a metabolic physician. Approvals valid for 2 Both:</li> <li>1 The patient has confirmed diagnosis of a specific mitochor</li> </ul>	n. 4 months for applica	tions meetir	ng the	following criteria:
2 The treatment remains appropriate and the patient is ber	nefiting from treatment			
TRIENTINE – Special Authority see SA2324 below – Retail pha Cap 250 mg		100	1	Trientine Waymade
SA2324 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals val the following criteria: All of the following:	lid without further rer	newal unless	s notif	ied for applications meeting
<ol> <li>Patient has confirmed Wilson disease; and</li> <li>Treatment with D-penicillamine has been trialled and dise effects or has not received sufficient benefit; and</li> <li>Treatment with zinc has been trailled and discontinued b</li> </ol>	ecause the person h	as experien	ced ir	ntolerable side effects or has
not received sufficient benefit, or zinc is considered clinic and requires copper chelation.	any mappropriate as	the person	nas s	symptomatic liver disease
Gaucher's Disease				
TALIGLUCERASE ALFA – Special Authority see SA2137 on th Inj 200 unit vial		pharmacy 1	1	Elelyso

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

#### ➡SA2137 Special Authority for Subsidy

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

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

**Renewal** only from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician. Approvals valid for 3 years for applications meeting the following criteria:

All of the following:

- 1 Patient has demonstrated a symptomatic improvement and has maintained improvements in the main symptom or symptoms for which therapy was started; and
- 2 Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size; and
- 3 Radiological (MRI) signs of bone activity performed at two years since initiation of treatment, and five yearly thereafter, demonstrate no deterioration shown by the MRI, compared with MRI taken immediately prior to commencement of therapy or adjusted dose; and
- 4 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
- 5 Patient is adherent with regular treatment and taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units).

#### Mouth and Throat

#### Agents Used in Mouth Ulceration

#### BENZYDAMINE HYDROCHLORIDE

Soln 0.15% – Higher subsidy of \$22.60 per 500 ml with Endorsement	9.00	500 ml	
	(22.60)	000 111	Difflam
Additional subsidy by endorsement for a patient who has prescription is endorsed accordingly.	oral mucositis a	as a result of tre	atment for cancer, and the
CARMELLOSE SODIUM WITH GELATIN AND PECTIN			
Paste	17.20	56.7 g OP	<ul> <li>Stomahesive</li> </ul>
	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

AThree 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

	Outerstate.		Euller	Busined an
	Subsidy (Manufacturer's P	rice) Subs	Fully	Brand or Generic
	\$	Per	1	Manufacturer
RIAMCINOLONE ACETONIDE				
Paste 0.1%	5.49	5 g OP	✓ ]	Kenalog in Orabase
Oropharyngeal Anti-infectives				
MPHOTERICIN B Lozenges 10 mg	E 96	20		Fungilin
<b>v v</b>		20	•	FullyIIII
IICONAZOLE Oral gel 20 mg per g	5 19	40 g OP	<b>~</b> 1	Decozol
YSTATIN		10 9 01		2000201
Oral liq 100,000 u per ml	2.22	24 ml OP	<b>√</b>	Nilstat
			-	
Vitamins				
Vitamin B				
YDROXOCOBALAMIN				
<ul> <li>Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a P</li> </ul>	SO3.95	3	<b>1</b>	Hydroxocobalamin
, ,			-	Panpharma
YRIDOXINE HYDROCHLORIDE				
a) No more than 100 mg per dose				
b) Only on a prescription	0.40	00		literation DO OF
Tab 25 mg – No patient co-payment payable     Tab 50 mg		90 500	-	<u>Vitamin B6 25</u> Pyridoxine
	20.40	500	•	multichem
HIAMINE HYDROCHLORIDE - Only on a prescription				
<ul> <li>Tab 50 mg</li> </ul>	4.65	100	✓ ·	Thiamine multichem
ITAMIN B COMPLEX				
<ul> <li>Tab, strong, BPC</li> </ul>	11.25	500	✓	Bplex
Vitamin C				
SCORBIC ACID				
a) No more than 100 mg per dose				
b) Only on a prescription				
b) Only on a prescription		500	•	Cvite
b) Only on a prescription Tab 100 mg	12.50	500	¥ (	Cvite
b) Only on a prescription Tab 100 mg	12.50	500	•	Cvite
<ul> <li>b) Only on a prescription</li> <li>Tab 100 mg</li> <li>Vitamin D</li> <li>LFACALCIDOL</li> </ul>		500		Cvite One-Alpha
b) Only on a prescription         F Tab 100 mg         Vitamin D         LFACALCIDOL         Cap 0.25 mcg         Cap 1 mcg			✓ ( ✓ (	One-Alpha One-Alpha
b) Only on a prescription         Tab 100 mg         Vitamin D         LFACALCIDOL         Cap 0.25 mcg         Cap 1 mcg		100	✓ ( ✓ (	One-Alpha
b) Only on a prescription Tab 100 mg Vitamin D LFACALCIDOL Cap 0.25 mcg Cap 1 mcg Oral drops 2 mcg per ml		100 100	✓ ( ✓ (	One-Alpha One-Alpha
b) Only on a prescription Tab 100 mg Vitamin D LFACALCIDOL Cap 0.25 mcg Cap 1 mcg Oral drops 2 mcg per ml ALCITRIOL		100 100	✓ () ✓ () ✓ ()	One-Alpha One-Alpha One-Alpha Calcitriol XL 529
b) Only on a prescription Tab 100 mg Vitamin D LFACALCIDOL Cap 0.25 mcg Cap 1 mcg Oral drops 2 mcg per ml ALCITRIOL Cap 0.25 mcg		100 100 20 ml OP 100		One-Alpha One-Alpha One-Alpha Calcitriol XL 529 Calcitriol-AFT
b) Only on a prescription Tab 100 mg Vitamin D LFACALCIDOL Cap 0.25 mcg Cap 1 mcg Oral drops 2 mcg per ml ALCITRIOL Cap 0.25 mcg		100 100 20 ml OP		One-Alpha One-Alpha One-Alpha Calcitriol XL 529 Calcitriol-AFT Calcitriol XL 529
b) Only on a prescription Tab 100 mg Vitamin D LFACALCIDOL Cap 0.25 mcg Oral drops 2 mcg per ml ALCITRIOL Cap 0.25 mcg Cap 0.5 mcg		100 100 20 ml OP 100		One-Alpha One-Alpha One-Alpha Calcitriol XL 529 Calcitriol-AFT
b) Only on a prescription Tab 100 mg Vitamin D LFACALCIDOL Cap 0.25 mcg Cap 1 mcg Oral drops 2 mcg per ml ALCITRIOL Cap 0.25 mcg		100 100 20 ml OP 100		One-Alpha One-Alpha One-Alpha Calcitriol XL 529 Calcitriol-AFT Calcitriol XL 529

fully subsidised
 Principal Supply

32

S29 Unapproved medicine supplied under Section 29 Sole Subsidised Supply

	Subsidy (Manufacturer's Price) \$	Fu Subsidise Per	,
Multivitamin Preparations			
MULTIVITAMIN RENAL – Special Authority see SA1546 below * Cap		30	Clinicians Renal Vit
► SA1546 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valit the following criteria: Either:	d without further rene	wal unless no	tified for applications meeting
<ol> <li>The patient has chronic kidney disease and is receiving e</li> <li>The patient has chronic kidney disease grade 5, defined a 15 ml/min/1.73 m<sup>2</sup> body surface area (BSA).</li> </ol>			
MULTIVITAMINS – Special Authority see SA1036 below – Reta * Powder		00 g OP •	Paediatric Seravit
■ SA1036 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals vali inborn errors of metabolism. Renewal from any relevant practitioner. Approvals valid without			·
approval for multivitamins. VITAMINS			
<ul> <li>* Tab (BPC cap strength)</li> <li>* Cap (fat soluble vitamins A, D, E, K) – Special Authority see</li> </ul>		1,000	/ Mvite
SA1720 below – Retail pharmacy		60 •	Vitabdeck
Initial application from any relevant practitioner. Approvals valithe following criteria:           Any of the following:         1           Patient has cystic fibrosis with pancreatic insufficiency; or         2           Patient is an infant or child with liver disease or short gut         3           Patient has severe malabsorption syndrome.         1		wal unless no	ified for applications meeting
Minerals			
Calcium			
CALCIUM CARBONATE * Tab 1.25 g (500 mg elemental) * Tab eff 1.25 g (500 mg elemental) – Subsidy by endorseme	nt260.00	100 •	Calci-Tab 500 Calcium 500 mg Hexal \$29
Subsidy by endorsement – Only when prescribed for pa considered unsuitable.	ediatric patients (< 5 y	/ears) where (	calcium carbonate oral liquid is
CALCIUM GLUCONATE  * Inj 10%, 10 ml ampoule		10 •	Max Health - Hameln 529
lodine			
POTASSIUM IODATE	5.00	00 -	
* Tab 253 mcg (150 mcg elemental iodine)	5.99	90 •	NeuroTabs

A 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) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer	
Iron					
FERROUS FUMARATE * Tab 200 mg (65 mg elemental)	3.49	100	✓ F	erro-tab	
FERROUS FUMARATE WITH FOLIC ACID * Tab 310 mg (100 mg elemental) with folic acid 350 mcg		100	- ✓ F	erro-F-Tabs	
FERROUS SULFATE			_	<u> </u>	
<ul> <li>* Tab long-acting 325 mg (105 mg elemental)</li> <li>* Oral liq 30 mg (6 mg elemental) per 1 ml</li> </ul>	9.25	30 250 ml	🖌 F	errograd erro-Liquid	
13.10       500 ml       ✓ Ferodan         IRON (AS FERRIC CARBOXYMALTOSE) – Special Authority see SA2394 on the next page – Retail pharmacy       Inj 50 mg per ml, 10 ml vial					

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Si	ubsidised	Generic	
\$	Per	~	Manufacturer	

#### ⇒SA2394 Special Authority for Subsidy

**Initial application** — (Anaemia) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with anaemia; and
- 2 Any of the following:
  - 2.1 Serum ferritin level is 20 mcg/L or less; or
  - 2.2 Both:
    - 2.2.1 Serum ferritin is between 20 and 50 mcg/L; and
    - 2.2.2 C-Reactive Protein (CRP) is at least 5 mg/L; or
  - 2.3 Patient has chronic inflammatory disease with symptoms of anaemia despite normal iron levels; and
- 3 Any of the following:
  - 3.1 Oral iron treatment has proven ineffective; or
  - 3.2 Oral iron treatment has resulted in dose-limiting intolerance; or
  - 3.3 Rapid correction of anaemia is required.

Renewal — (Anaemia) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient continues to have anaemia with a serum ferritin level of 20 mcg/L, or less or between 20 and 50 mcg/L with CRP of at least 5 mg/L, or has chronic inflammatory disease with symptoms of anaemia despite normal iron levels; and
- 2 A trial (or re-trial) with oral iron is clinically inappropriate.

Initial application — (iron deficiency anaemia) only from an internal medicine physician, obstetrician, gynaecologist, anaesthetist or medical practitioner on the recommendation of a internal medicine physician, obstetrician, gynaecologist or anaesthetist. Approvals valid for 3 months for applications meeting the following criteria: Both:

- 1 Patient has been diagnosed with iron-deficiency anaemia; and
- 2 Any of the following:
  - 2.1 Patient has been compliant with oral iron treatment and treatment has proven ineffective; or
  - 2.2 Treatment with oral iron has resulted in dose-limiting intolerance; or
  - 2.3 Patient has symptomatic heart failure, chronic kidney disease stage 3 or more or active inflammatory bowel disease and a trial of oral iron is unlikely to be effective; or
  - 2.4 Rapid correction of anaemia is required.

Renewal — (iron deficiency anaemia) only from an internal medicine physician, obstetrician, gynaecologist, anaesthetist or medical practitioner on the recommendation of a internal medicine physician, obstetrician, gynaecologist or anaesthetist. Approvals valid for 3 months for applications meeting the following criteria: Both:

1 Patient continues to have iron-deficiency anaemia; and

2 A re-trial with oral iron is clinically inappropriate.

#### **IRON POLYMALTOSE**

* Inj 50 mg per ml, 2 ml ampoule	5	✓ Ferrosig
Magnesium		
MAGNESIUM HYDROXIDE Suspension 8%	355 ml	✓ Phillips Milk of Magnesia <sup>S29</sup>
MAGNESIUM SULPHATE           * Inj 2 mmol per ml, 5 ml ampoule           * Inj 2 mmol per ml, 10 ml ampoule		<ul> <li>✓ <u>Martindale</u></li> <li>✓ Inresa S29</li> </ul>

	Subsidy (Manufacturer's Price) \$	Subsid Per	Fully lised	Brand or Generic Manufacturer
Zinc				
ZINC SULPHATE * Cap 137.4 mg (50 mg elemental)	11.00	100	🗸 Zi	ncaps

Subsidised

Per

Fully

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

Manufacturer

## Antianaemics

### Hypoplastic and Haemolytic

#### ➡SA2266 Special Authority for Subsidy

**Initial application** — (chronic renal failure) from any relevant practitioner. 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.

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

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

EPOETIN ALFA - Special Authority see SA2266 above - Retail pharmacy

Wastage claimable

Inj 1,000 iu in 0.5 ml, syringe	 6	<ul> <li>Binocrit</li> </ul>
Inj 2,000 iu in 1 ml, syringe	 6	<ul> <li>Binocrit</li> </ul>
Inj 3,000 iu in 0.3 ml, syringe	6	<ul> <li>Binocrit</li> </ul>
Inj 4,000 iu in 0.4 ml, syringe	6	<ul> <li>Binocrit</li> </ul>
Inj 5,000 iu in 0.5 ml, syringe	6	<ul> <li>Binocrit</li> </ul>
Inj 6,000 iu in 0.6 ml, syringe	6	<ul> <li>Binocrit</li> </ul>
Inj 8,000 iu in 0.8 ml, syringe	6	<ul> <li>Binocrit</li> </ul>
Inj 10,000 iu in 1 ml, syringe	6	<ul> <li>Binocrit</li> </ul>
Inj 40,000 iu in 1 ml, syringe	1	<ul> <li>Binocrit</li> </ul>

	Subsidy (Manufacturer's Price) \$	Subsi Per	Fully idised	Brand or Generic Manufacturer
Megaloblastic				
FOLIC ACID * Tab 0.8 mg		1,000	✔ F	olic Acid multichem
* Tab 5 mg Oral liq 50 mcg per ml		100 5 ml OP		olic Acid Viatris iomed
Antifibrinolytics, Haemostatics and Local Scl	erosants			

### EFTRENONACOG ALFA [RECOMBINANT FACTOR IX] - [Xpharm]

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

Inj 250 iu vial		<u> </u>	<ul> <li>Alprolix</li> </ul>
Inj 500 iu vial		1	<ul> <li>Alprolix</li> </ul>
Inj 1,000 iu vial		1	Alprolix
Inj 2,000 iu vial		1	<ul> <li>Alprolix</li> </ul>
Inj 3,000 iu vial		1	<ul> <li>Alprolix</li> </ul>
Inj 4,000 iu vial		1	<ul> <li>Alprolix</li> </ul>
ELTROMBOPAG – Special Authority see SA1743 be Wastage claimable	elow – Retail pharmacy		
Tab 25 mg		28	Revolade
Tab 50 mg	-	28	<ul> <li>Revolade</li> </ul>

### ► SA1743 Special Authority for Subsidy

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

All of the following:

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

**Initial application** — (idiopathic thrombocytopenic purpura - preparation for splenectomy) only from a haematologist. Approvals valid for 6 weeks where the patient requires eltrombopag treatment as preparation for splenectomy.

**Initial application** — (idiopathic thrombocytopenic purpura contraindicated to splenectomy) only from a haematologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

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

Subsidy	F	ully	Brand or	
(Manufacturer's Price)	Subsidi	sed	Generic	
\$	Per	✓	Manufacturer	

continued...

and significant mucocutaneous bleeding.

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

Both:

1 Two immunosuppressive therapies have been trialled and failed after therapy of at least 3 months duration; and

- 2 Either:
  - 2.1 Patient has severe aplastic anaemia with a platelet count of less than or equal to 20,000 platelets per microliter; or
  - 2.2 Patient has severe aplastic anaemia with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding.

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

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

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

All of the following:

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

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

Both:

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

EMICIZUMAB - [Xpharm] - Special Authority see SA2272 below

Inj 30 mg in 1 ml vial		1	<ul> <li>Hemlibra</li> </ul>
Inj 60 mg in 0.4 ml vial	7,138.00	1	<ul> <li>Hemlibra</li> </ul>
Inj 105 mg in 0.7 ml vial		1	<ul> <li>Hemlibra</li> </ul>
Inj 150 mg in 1 ml vial	17,846.00	1	<ul> <li>Hemlibra</li> </ul>

#### ➡SA2272 Special Authority for Subsidy

Initial application — (Severe Haemophilia A with or without FVIII inhibitors) only from a haematologist. Approvals valid without further renewal unless notified for applications meeting the following criteria: Both:

- Both:
  - 1 Patient has severe congenital haemophilia A with a severe bleeding phenotype (endogenous factor VIII activity less than or equal to 2%); and
  - 2 Emicizumab is to be administered at a dose of no greater than 3 mg/kg weekly for 4 weeks followed by the equivalent of 1.5 mg/kg weekly.

### 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 syringe1,178.30	1	NovoSeven RT
Inj 2 mg syringe2,356.60	1	NovoSeven RT
Inj 5 mg syringe	1	NovoSeven RT
Inj 8 mg syringe9,426.40	1	NovoSeven RT

<sup>▲</sup>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
ACTOR EIGHT INHIBITOR BYPASSING FRACTION - [Xpha				
For patients with haemophilia. Preferred Brand of bypassin				
is managed by the Haemophilia Treaters Group in conjuncti				
Inj 500 U		1		FEIBA NF
Inj 1,000 U	'	1		FEIBA NF
Inj 2,500 U		1	•	FEIBA NF
IOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] - [Xpha				
For patients with haemophilia. Rare Clinical Circumstances				
treatment is managed by the Haemophilia Treaters Group in	i conjunction with the	Nation	nal Haemo	philia Management Group,
subject to criteria. Inj 250 iu prefilled syringe	007 E0	1		Xyntha
Inj 500 iu prefilled syringe		1		Xyntha
Inj 1,000 iu prefilled syringe		1		Xyntha
Inj 2,000 iu prefilled syringe		1		Xvntha
Inj 3,000 iu prefilled syringe		1		Xyntha
IONACOG GAMMA, [RECOMBINANT FACTOR IX] – [Xpharm			-	хуппа
For patients with haemophilia. Access to funded treatment		مسمم	hilia Troat	ere Group in conjunction
with the National Haemophilia Management Group.	is managed by the ha	emop		
Inj 1.000 iu vial	870.00	1	1	RIXUBIS
Inj 2,000 iu vial		1		RIXUBIS
Inj 3,000 iu vial	,	1		RIXUBIS
•				
<ul> <li>CTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE) – For patients with haemophilia. Preferred Brand of short hall</li> </ul>		or VIII	Access to	funded treatment is
managed by the Haemophilia Treaters Group in conjunction				
Inj 500 iu vial		1		Advate
Inj 1,000 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 funder
treatment is managed by the Haemophilia Treaters Group in				
subject to criteria.				printe management en cap
Inj 250 iu vial		1	1	Kogenate FS
Inį 500 iu vial		1		Kogenate FS
Inj 1,000 iu vial	950.00	1	✓	Kogenate FS
Inj 2,000 iu vial	1,900.00	1	✓	Kogenate FS
Inj 3,000 iu vial	2,850.00	1	✓	Kogenate FS
RURIOCTOCOG ALFA PEGOL [RECOMBINANT FACTOR VIII]	] – [Xpharm]			
For patients with haemophilia A receiving prophylaxis treatm		d trea	tment is m	nanaged by the Haemophil
Treaters Group in conjunction with the National Haemophilia				
Inj 1,000 iu vial	1,200.00	1	✓	Adynovate
Inj 2,000 iu vial		1	✓	Adynovate
ODIUM TETRADECYL SULPHATE				
k lnj 3% 2 ml		5		
,	(73.00)	-		Fibro-vein
RANEXAMIC ACID	· · · /			
Tab 500 mg	10.45	60	1	Mercury Pharma
	45.68	100		Cyklokapron
Cyklokapron Tab 500 mg to be delisted 1 November 2025)	10.00		-	

	Subsidy (Manufacturer's Price) \$	Sı Per	Fully Ibsidised	Brand or Generic Manufacturer
Vitamin K				
PHYTOMENADIONE Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSO	8.00	5	✔ К	Conakion MM Paediatric
Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO	9.21	5	🗸 К	Conakion MM
Antithrombotic Agents				
Antiplatelet Agents				
ASPIRIN ₭ Tab 100 mg	12.65	990	✓ <u>E</u>	thics Aspirin EC
CLOPIDOGREL ★ Tab 75 mg	5.07	84	✓ A	rrow - Clopid
DIPYRIDAMOLE Tab long-acting 150 mg		60	<b>√</b> P	ytazen SR
TICAGRELOR – Special Authority see SA1955 below – Retail pr * Tab 90 mg		56	✓ <u>⊺</u>	icagrelor Sandoz

### ⇒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:

Both:

- 1 Either:
  - 1.1 Patient has had a neurological stenting procedure\* in the last 60 days; or
  - 1.2 Patient is about to have a neurological stenting procedure performed\*; and

2 Either:

- 2.1 Patient has demonstrated clopidogrel resistance using the P2Y12 (VerifyNow) assay or another appropriate platelet function assay and requires antiplatelet treatment with ticagrelor; or
- 2.2 Either:
  - 2.2.1 Clopidogrel resistance has been demonstrated by the occurrence of a new cerebral ischemic event; or
  - 2.2.2 Clopidogrel resistance has been demonstrated by the occurrence of transient ischemic attack symptoms referable to the stent.

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

All of the following:

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

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

Subsidy		Fully	/ Brand	or
(Manufacturer's Pric	e)	Subsidised	l Generi	ic
\$	Pe	er 🗸	Manufa	acturer

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

Both:

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

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

Both:

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

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

All of the following:

- 1 Patient has undergone percutaneous coronary intervention; and
- 2 Patient has had a stent deployed in the previous 4 weeks; and
- 3 Patient is clopidogrel-allergic\*\*.
- Notes: indications marked with \* are unapproved indications.

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

## Heparin and Antagonist Preparations

ENOXAPARIN SODIUM - Special Authority see SA2152 below - Retail pharmacy

Inj 20 mg in 0.2 ml syringe	21.90	10	<ul> <li>Clexane</li> </ul>
Inj 40 mg in 0.4 ml syringe		10	<ul> <li>Clexane</li> </ul>
Inj 60 mg in 0.6 ml syringe		10	<ul> <li>Clexane</li> </ul>
Inj 80 mg in 0.8 ml syringe		10	<ul> <li>Clexane</li> </ul>
Inj 100 mg in 1 ml syringe		10	<ul> <li>Clexane</li> </ul>
Inj 120 mg in 0.8 ml syringe		10	<ul> <li>Clexane Forte</li> </ul>
Inj 150 mg in 1 ml syringe		10	<ul> <li>Clexane Forte</li> </ul>

### ⇒SA2152 Special Authority for Subsidy

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

Any of the following:

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

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

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

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

continued...

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

continued...

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

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

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

Any of the following:

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

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

HEPARIN SODIUM

Inj 1,000 iu per ml, 10 ml vial		25	<ul> <li>Pfizer S29</li> </ul>
Inj 1,000 iu per ml, 5 ml ampoule		10	Wockhardt S29
	103.70		Wockhardt PSF S29
	127.44	50	<ul> <li>Pfizer</li> </ul>
Inj 5,000 iu per ml, 5 ml vial		10	<ul> <li>Heparin Sodium</li> <li>Panpharma</li> </ul>
Inj 5,000 iu per ml, 1 ml		5	<ul> <li>Hospira</li> </ul>
Inj 25,000 iu per ml, 0.2 ml		5	<ul> <li>Hospira</li> </ul>
	482.20	50	✓ Heparin DBL <sup>S29</sup>
(Heparin DBL <sup>\$23</sup> Inj 25,000 iu per ml, 0.2 ml to be delist HEPARINISED SALINE	,	50	·
Inj 10 iu per ml, 5 ml		50	<ul> <li>Pfizer</li> </ul>
Oral Anticoagulants			
DABIGATRAN			
Cap 75 mg – No more than 2 cap per day		60	<ul> <li>Pradaxa</li> </ul>
Cap 110 mg		60	<ul> <li>Pradaxa</li> </ul>
Cap 150 mg		60	<ul> <li>Pradaxa</li> </ul>
RIVAROXABAN			
Tab 10 mg – No more than 1 tab per day		30	✓ Xarelto
Tab 15 mg – Up to 14 tab available on a PSO		28	✓ Xarelto
Tab 20 mg		28	✓ Xarelto
WARFARIN SODIUM			
Note: Marevan and Coumadin are not interchangeable	le.		
* Tab 1 mg	3.46	50	<ul> <li>Coumadin</li> </ul>
	7.50	100	<ul> <li>Marevan</li> </ul>
* Tab 2 mg	4.31	50	<ul> <li>Coumadin</li> </ul>
* Tab 3 mg		100	<ul> <li>Marevan</li> </ul>
* Tab 5 mg		50	<ul> <li>Coumadin</li> </ul>
	13.50	100	<ul> <li>Marevan</li> </ul>

▲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
Blood Colony-stimulating Factors				
FILGRASTIM – Special Authority see SA1259 below – Retail pl	narmacy			
Inj 300 mcg per 0.5 ml prefilled syringe		10		ivestim
Inj 480 mcg per 0.5 ml prefilled syringe		10	✓ <u>N</u>	ivestim
SA1259 Special Authority for Subsidy				
nitial application only from a relevant specialist, vocationally re				
recommendation of a relevant specialist. Approvals valid without	it further renewal unles	ss no	tified for app	lications meeting the
ollowing criteria: Any of the following:				
1 Prevention of neutropenia in patients undergoing high ris	k chemotherapy for ca	ncer	(febrile neut	ropenia risk greater than
or equal to 20%*); or			(	openia neit greater alan
2 Peripheral blood stem cell mobilisation in patients underg	joing haematological t	ransp	plantation; or	
3 Peripheral blood stem cell mobilisation or bone marrow d		donoi	s for transpla	antation; or
4 Treatment of severe chronic neutropenia (ANC < 0.5 ×10				
5 Treatment of drug-induced prolonged neutropenia (ANC	,			and for a discussion
Note: *Febrile neutropenia risk greater than or equal to 20% aft European Organisation for Research and Treatment of Cancer (	•	other	risk factors a	as defined by the
PEGFILGRASTIM – Special Authority see SA1912 below – Ret				
Inj 6 mg per 0.6 ml syringe	65.00	1	_	extenzo
			✓ Z	iextenzo AU
Ziextenzo AU Inj 6 mg per 0.6 ml syringe to be delisted 1 Augus	ST 2025)			
⇒SA1912 Special Authority for Subsidy				
nitial application only from a relevant specialist, vocationally re recommendation of a relevant specialist. Approvals valid without				

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			Biomed Biomed
* Inj 75 mg per ml, 10 ml	5.00 5	<ul> <li>✓</li> </ul>	Juno LumaCina Pfizer S29
	4 70		Biomed
Inj 8.4%, 50 ml24 a) Up to 5 inj available on a PSO b) Not in combination	4.70 1	v	Biomea
Inj 8.4%, 100 ml25 a) Up to 5 inj available on a PSO b) Not in combination	5.31 1	<b>√</b>	Biomed

	Subsidy		Fully	Brand or
	(Manufacturer's Pric \$	e) Subs Per	sidised	Generic Manufacturer
SODIUM CHLORIDE	Ŷ			manufacturor
Not funded for use as a nasal drop. Not funded for nebulis	ser use except when	used in coni	unction	with an antibiotic intende
for nebuliser use.		acca in conj	anotion	
Inj 23.4% (4 mmol/ml), 20 ml ampoule	40.15	5	🗸 В	liomed
For Sodium chloride oral liquid formulation refer Stand		283		
Inj 0.9%, 5 ml ampoule – Up to 5 inj available on a PSO		20		resenius Kabi
Inj 0.9%, 10 ml ampoule - Up to 5 inj available on a PSO.		50		resenius Kabi
Inj 0.9%, 20 ml ampoule		20	-	resenius Kabi axter
Inj 0.9%, 1,000 ml bag – Up to 2 bag available on a PSO . Only if prescribed on a prescription for renal dialysis, n		1 I caro in the	_	
for emergency use. (500 ml and 1,000 ml packs)	naternity of post-nata	a care in the	nome	of the patient, of on a FS
Inj 0.9%, 500 ml bag – Up to 4 bag available on a PSO	1.53	1	✓ В	axter
Only if prescribed on a prescription for renal dialysis, n				
for emergency use. (500 ml and 1,000 ml packs)	5 1			1 /
TOTAL PARENTERAL NUTRITION (TPN)				
Infusion	CBS	1 OP	🗸 T	PN
VATER				
1) On a prescription or Practitioner's Supply Order only	when on the same for	orm as an ini	ection li	sted in the Pharmaceuti
Schedule requiring a solvent or diluent; or		in ao an inj		
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 pa	atients only.		
		-		
Inj 10 ml ampoule – Up to 5 inj available on a PSO		50		lultichem
		-		lultichem resenius Kabi
Inj 10 ml ampoule – Up to 5 inj available on a PSO		50		
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration		50		
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration	7.60 	50 20	✔ F	
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder	7.60 	50	✔ F	resenius Kabi
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder		50 20	✓ F	resenius Kabi
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO		50 20 300 g OP	✓ F	resenius Kabi alcium Resonium
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE		50 20 300 g OP	✓ F ✓ C ✓ E	resenius Kabi alcium Resonium lectral
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES		50 20 300 g OP 50	✓ F ✓ C ✓ E	resenius Kabi alcium Resonium
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE		50 20 300 g OP 50	✓ F ✓ C ✓ E	resenius Kabi calcium Resonium lectral lydralyte -
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes		50 20 300 g OP 50	✓ F ✓ C ✓ E ✓ H	resenius Kabi calcium Resonium lectral lydralyte -
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes		50 20 300 g OP 50 1 OP	✓ F ✓ C ✓ E ✓ H	resenius Kabi calcium Resonium lectral lydralyte - Lemonade
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSI Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol)		50 20 300 g OP 50 1 OP	✓ F ✓ C ✓ E ✓ H	resenius Kabi calcium Resonium lectral lydralyte - Lemonade
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSS Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE		50 20 300 g OP 50 1 OP 100	✓ F ✓ C ✓ E ✓ H	resenius Kabi calcium Resonium lectral lydralyte - Lemonade
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes		50 20 300 g OP 50 1 OP 100	✓ F ✓ C ✓ E ✓ H ✓ P	resenius Kabi calcium Resonium lectral lydralyte - Lemonade hosphate Phebra
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE * Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)		50 20 300 g OP 50 1 OP 100 60	✓ F ✓ C ✓ E ✓ H ✓ P	resenius Kabi Falcium Resonium Fectral lydralyte - Lemonade hosphate Phebra
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE ★ Tab long-acting 600 mg (8 mmol)		50 20 300 g OP 50 1 OP 100 60	✓ F ✓ C ✓ E ✓ H ✓ P	resenius Kabi Falcium Resonium Fectral lydralyte - Lemonade hosphate Phebra
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE It Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq) Tab long-acting 600 mg (8 mmol) CODIUM BICARBONATE		50 20 300 g OP 50 1 OP 100 60 200	✓ F ✓ C ✓ E ✓ H ✓ P ✓ S	resenius Kabi Falcium Resonium Fectral Iydralyte - Lemonade Ihosphate Phebra Fhiorvescent pan-K
Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO Oral Administration CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE ★ Tab long-acting 600 mg (8 mmol) SODIUM BICARBONATE		50 20 300 g OP 50 1 OP 100 60 200	✓ F ✓ C ✓ E ✓ H ✓ P ✓ S	resenius Kabi Falcium Resonium Jectral Ivdralyte - Lemonade hosphate Phebra Shlorvescent pan-K

▲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		Fully Brand or
	(Manufacturer's Price \$	e) S Per	Subsidised Generic Manufacturer
Alpha-Adrenoceptor Blockers			
Alpha Adrenoceptor Blockers			
DOXAZOSIN			
₭ Tab 2 mg		500	<ul> <li>Doxazosin Clinect</li> </ul>
🛠 Tab 4 mg	20.94	500	<ul> <li>Doxazosin Clinect</li> </ul>
PHENOXYBENZAMINE HYDROCHLORIDE			
🖌 Cap 10 mg	65.00	30	BNM \$29
PRAZOSIN			
€ Tab 1 mg	5.53	100	Arrotex-Prazosin
			S29 S29
	9.98		✓ Minipress S29
€ Tab 2 mg		100	✓ Arrotex-Prazosin
č			S29 S29
	13.29		✓ Minipress S29
፦ Tab 5 mg		100	✓ Arrotex-Prazosin
			S29 S29
	22.00		✓ Minipress S29
Cap 1 mg		100	<ul> <li>Prazosin Mylan S29</li> </ul>
		100	<ul> <li>Prazosin Mylan S29</li> <li>Prazosin Mylan S29</li> </ul>
			•
K Cap 5 mg	23.32	100	<ul> <li>Prazosin Mylan S29</li> </ul>
Agents Affecting the Renin-Angiotensin System	n		
ACE Inhibitors			
CAPTOPRIL			
APTOPRIL		100 ml O	P 🗸 DP-Captopril
APTOPRIL		100 ml O	P 🖌 <u>DP-Captopril</u>
APTOPRIL Coral liq 5 mg per ml Oral liquid restricted to children under 12 years of age.		100 ml O	P 🖌 <u>DP-Captopril</u>
APTOPRIL Cral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE		100 ml O 90	P ✓ <u>DP-Captopril</u> ✓ Acetec
APTOPRIL Cral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE Tab 5 mg	1.75		
APTOPRIL Cral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE Tab 5 mg Tab 10 mg	1.75 1.97	90	✓ Acetec
APTOPRIL Coral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE Tab 5 mg Tab 10 mg Tab 20 mg	1.75 1.97	90 90	✓ Acetec ✓ Acetec
APTOPRIL ← Oral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE ← Tab 5 mg	1.75 1.97 2.35	90 90 90	✓ Acetec ✓ Acetec ✓ Acetec
APTOPRIL Cral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE Tab 5 mg Tab 10 mg Tab 20 mg SINOPRIL	1.75 1.97 2.35	90 90	<ul> <li>✓ Acetec</li> <li>✓ Acetec</li> <li>✓ Acetec</li> <li>✓ Ethics Lisinopril</li> </ul>
APTOPRIL ← Oral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE ← Tab 5 mg ← Tab 10 mg ← Tab 20 mg ISINOPRIL ← Tab 5 mg	1.75 1.97 2.35 11.07	90 90 90	✓ Acetec ✓ Acetec ✓ Acetec
APTOPRIL	1.75 1.97 2.35 11.07 11.67	90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> </ul>
APTOPRIL ← Oral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE ← Tab 5 mg	1.75 1.97 2.35 11.07 11.67	90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> </ul>
<ul> <li>APTOPRIL</li> <li>♦ Oral liq 5 mg per ml</li> <li>Oral liquid restricted to children under 12 years of age.</li> <li>INALAPRIL MALEATE</li> <li>♦ Tab 5 mg</li> <li>♦ Tab 10 mg</li> <li>♦ Tab 20 mg</li> <li>♦ Tab 5 mg</li> <li>♦ Tab 10 mg</li> <li>♦ Tab 10 mg</li> <li>♦ Tab 20 mg</li> <li>♦ Tab 20 mg</li> </ul>	1.75 1.97 2.35 11.07 11.67	90 90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> </ul>
APTOPRIL ← Oral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE ← Tab 5 mg	1.75 1.97 2.35 11.07 11.67	90 90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> </ul>
APTOPRIL ← Oral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE ← Tab 5 mg	1.75 1.97 2.35 11.07 11.67	90 90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> </ul>
APTOPRIL ← Oral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE ← Tab 5 mg	1.75 1.97 2.35 11.07 11.67	90 90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> </ul>
APTOPRIL € Oral liq 5 mg per ml Oral liquid restricted to children under 12 years of age. NALAPRIL MALEATE € Tab 5 mg	1.75 1.97 2.35 11.07 11.67	90 90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Teva Lisinopril</li> </ul>
<ul> <li>APTOPRIL</li> <li>✓ Oral liq 5 mg per ml</li></ul>		90 90 90 90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Teva Lisinopril</li> </ul>
CAPTOPRIL		90 90 90 90 90 90	<ul> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Acetec</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Teva Lisinopril</li> <li>Ethics Lisinopril</li> <li>Teva Lisinopril</li> <li>Teva Lisinopril</li> </ul>

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic ✓ Manufacturer
QUINAPRIL			
* Tab 5 mg		90	Arrow-Quinapril 5
* Tab 10 mg	12.51	90	<ul> <li>Arrow-Quinapril 10</li> </ul>
* Tab 20 mg	14.83	90	<ul> <li>Arrow-Quinapril 20</li> </ul>
RAMIPRIL			
* Cap 1.25 mg	17.25	90	✓ <u>Tryzan</u>
卷 Сар 2.5 mg	16.50	90	✓ <u>Tryzan</u>
* Сар 5 mg	16.88	90	<ul> <li>Tryzan</li> </ul>
* Cap 10 mg	17.63	90	<ul> <li><u>Tryzan</u></li> </ul>
Angiotensin II Antagonists			
CANDESARTAN CILEXETIL			
* Tab 4 mg	2.68	90	<ul> <li>Candestar</li> </ul>
🖌 Tab 8 mg	2.67	90	✓ Candestar
K Tab 16 mg	4.22	90	✓ Candestar
🖌 Tab 32 mg	5.24	90	✓ Candestar
OSARTAN POTASSIUM			
🖌 Tab 12.5 mg	2.00	84	Losartan Actavis
🖌 Tab 25 mg	2.29	84	<ul> <li>Losartan Actavis</li> </ul>
🖌 Tab 50 mg	2.86	84	<ul> <li>Losartan Actavis</li> </ul>
🖌 Tab 100 mg	4.57	84	<ul> <li>Losartan Actavis</li> </ul>
Angiotensin II Antagonists with Diuretics			
ANDESARTAN CILEXETIL WITH HYDROCHLOROTHIAZIDE	-		
Tab 16 mg with hydrochlorothiazide 12.5 mg	4.10	30	<ul> <li>APO-Candesartan HCTZ 16/12.5</li> </ul>
* Tab 32 mg with hydrochlorothiazide 12.5 mg	5.25	30	<ul> <li>APO-Candesartan HCTZ 32/12.5</li> </ul>
OSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE			
Tab 50 mg with hydrochlorothiazide 12.5 mg	4.00	30	<ul> <li>Arrow-Losartan &amp; Hydrochlorothiazide</li> </ul>

### Angiotensin II Antagonists with Neprilysin Inhibitors

SACUBITRIL WITH VALSARTAN – Special Authority see SA	2302 below – Retail p	oharmacy	
Tab 24.3 mg with valsartan 25.7 mg		56	<ul> <li>Entresto 24/26</li> </ul>
Tab 48.6 mg with valsartan 51.4 mg		56	<ul> <li>Entresto 49/51</li> </ul>
Tab 97.2 mg with valsartan 102.8 mg		56	<ul> <li>Entresto 97/103</li> </ul>

### ⇒SA2302 Special Authority for Subsidy

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

All of the following:

- 1 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

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

- 2.3 Patient is in NYHA/WHO functional class IV; and
- 3 Either:
  - 3.1 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; or
  - 3.2 An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment; and
- 4 Patient is receiving concomitant optimal standard chronic heart failure treatments.

Antiarrhythmics

For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaest	thetics, Local, pa	age 123	
AMIODARONE HYDROCHLORIDE			
▲ Tab 100 mg	3.49	30	<ul> <li>Aratac</li> </ul>
▲ Tab 200 mg	4.49	30	<ul> <li>Aratac</li> </ul>
Inj 50 mg per ml, 3 ml ampoule – Up to 10 inj available on a			
PSO	15.22	10	<ul> <li>Max Health</li> </ul>
ATROPINE SULPHATE			
* Inj 600 mcg per ml, 1 ml ampoule - Up to 5 inj available on a			
PSO		10	<ul> <li>Hikma S29</li> </ul>
			Juno S29
			✓ Martindale
(Juno S29 Inj 600 mcg per ml, 1 ml ampoule to be delisted 1 Octo	ober 2025)		
DIGOXIN			
* Tab 62.5 mcg – Up to 30 tab available on a PSO	7.80	240	Lanoxin PG
* Tab 250 mcg – Up to 30 tab available on a PSO		240	<ul> <li>Lanoxin</li> </ul>
* Oral liq 50 mcg per ml		60 ml	<ul> <li>Lanoxin</li> </ul>
			Lanoxin S29 S29
DISOPYRAMIDE PHOSPHATE			
▲ Cap 100 mg		100	<ul> <li>Rythmodan</li> </ul>
	55.90	84	<ul> <li>Rythmodan -</li> </ul>
			Cheplafarm S29
(Rythmodan Cap 100 mg to be delisted 1 November 2025)			•
▲ Tab 50 mg	19.95	60	<ul> <li>Flecainide BNM</li> </ul>
▲ Cap long-acting 100 mg		90	✓ Flecainide
3			Controlled
			Release Teva
▲ Cap long-acting 200 mg	54.28	90	<ul> <li>Flecainide</li> </ul>
			Controlled
			Release Teva
Inj 10 mg per ml, 15 ml ampoule	102.79	5	Almarytm S29
	108.16		<ul> <li>Tambocor</li> </ul>
			<ul> <li>Tambocor</li> </ul>
			German S29
MEXILETINE HYDROCHLORIDE			
▲ Cap 150 mg	162.00	100	<ul> <li>Teva S29</li> </ul>
▲ Cap 250 mg	202.00	100	<ul> <li>Teva S29</li> </ul>
· •			

Λ)	Subsidy /anufacturer's Price) \$	S Per	Fully ubsidised	Brand or Generic Manufacturer
PROPAFENONE HYDROCHLORIDE ▲ Tab 150 mg	40.90	50	✓ R	lytmonorm
Antihypotensives				
MIDODRINE – Special Authority see SA1474 below – Retail pharm	acy			
Tab 2.5 mg		100		IAR-Midodrine <sup>®29</sup> <u>Iidodrine</u> Medsurge
Tab 5 mg	58.88	100		IAR-Midodrine S29 <u>Nidodrine</u> Medsurge
(MAR-Midodring Sign Tab 2.5 mg to be delisted 1 October 2025)				

(MAR-Midodrine S29) Tab 2.5 mg to be delisted 1 October 2025)

(MAR-Midodrine S29) Tab 5 mg to be delisted 1 October 2025)

### 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.

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

## **Beta-Adrenoceptor Blockers**

### **Beta Adrenoceptor Blockers**

----

ATENOLOL			
* Tab 50 mg		500	✓ Viatris
* Tab 100 mg		500	<ul> <li>Atenolol Viatris</li> </ul>
		300 ml OP	✓ Atenolol AFT
Restricted to children under	12 years of age.		
BISOPROLOL FUMARATE			
* Tab 2.5 mg		90	Ipca-Bisoprolol
		90	✓ Ipca-Bisoprolol
		90	✓ Ipca-Bisoprolol
CARVEDILOL			<u></u>
	2.24	60	<ul> <li>Carvedilol Sandoz</li> </ul>
		60	<ul> <li>Carvedilol Sandoz</li> <li>Carvedilol Sandoz</li> </ul>
		•••	<ul> <li>Carvedilol Sandoz</li> <li>Carvedilol Sandoz</li> </ul>
· · · · · · · · · · · · · · · · · · ·		60	<ul> <li>Carvedilor Sandoz</li> </ul>
LABETALOL			
* Tab 100 mg		100	<ul> <li>Trandate</li> </ul>
	49.54		<ul> <li>Biocon S29</li> </ul>
* Tab 200 mg		100	<ul> <li>Trandate</li> </ul>
		5	
	(88.60)		Trandate
METOPROLOL SUCCINATE			
* Tab long-acting 23.75 mg		90	Myloc CR
		90	✓ Myloc CR
		90	✓ Myloc CR
		90	✓ Myloc CR
		50	- myroo on

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
METOPROLOL TARTRATE				
* Tab 50 mg	5.66	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		5	✓	Metoprolol IV Mylan
			✓	Metoprolol IV Viatris
NADOLOL				
* Tab 40 mg		100	1	Nadolol BNM
* Tab 80 mg		100	✓	Nadolol BNM
PROPRANOLOL				
* Tab 10 mg	7.04	100	✓	Drofate
* Tab 40 mg		100	✓	IPCA-Propranolol
* Cap long-acting 160 mg		100		Cardinol LA
* Oral lig 4 mg per ml - Special Authority see SA1327 below				
Retail pharmacy		500 m	nl 🗸	Hikma-
				Propranolol S29
			1	Roxane-
				Propranolol \$29

### ⇒SA1327 Special Authority for Subsidy

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

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

Renewal 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.

### SOTAL OL

*	Tab 80 mg	300	<ul> <li>Sotalol Viatris S29</li> </ul>
	37.50	500	🗸 Mylan
*	Tab 160 mg14.00	100	🗸 Mylan

## **Calcium Channel Blockers**

### Dihydropyridine Calcium Channel Blockers

• • • •			
AMLODIPINE			
* Tab 2.5 mg	1.45	90	<ul> <li>Vasorex</li> </ul>
* Tab 5 mg		90	<ul> <li>Vasorex</li> </ul>
* Tab 10 mg	1.31	90	✓ Vasorex
FELODIPINE			
* Tab long-acting 2.5 mg	2.18	30	Plendil ER
* Tab long-acting 5 mg		90	<ul> <li>Felo 5 ER</li> </ul>
* Tab long-acting 10 mg		90	<ul> <li>Felo 10 ER</li> </ul>

50

#### Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per Manufacturer NIFEDIPINE 56 ✓ Tensipine MR10 S29 Subsidised for patients who were taking nifedipine tab long-acting 10 mg prior to 1 July 2023 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of nifedipine tab long-acting 10 mg. Nyefax Retard \* 100 \* Tab long-acting 30 mg......4.78 14 Mylan Italy (24 hr release) \$29 34.10 100 Mylan (24 hr release) \$29 Tab long-acting 60 mg......52.81 100 Mvlan (24 hr release) \$29 Other Calcium Channel Blockers DILTIAZEM HYDROCHLORIDE Diltiazem CD Clinect 500 \* Cap long-acting 180 mg ......7.00 30 Cardizem CD \* Cap long-acting 240 mg ......9.30 30 Cardizem CD PERHEXILINE MALEATE 100 Pexsia VERAPAMIL HYDROCHLORIDE 100 Isoptin Tab 80 mg ......11.74 100 ✓ Isoptin \* Isoptin Retard \$29 \* 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 Isoptin 5 **Centrally-Acting Agents** CLONIDINE \* Patch 2.5 mg, 100 mcg per day - Only on a prescription......11.70 Mvlan 4 4 🗸 Mylan Patch 7.5 mg, 300 mcg per day - Only on a prescription......17.90 4 Mylan \* CLONIDINE HYDROCHLORIDE Clonidine Teva 112 100 Catapres 5 Catapres MFTHYI DOPA ✓ Methyldopa Viatris 100 Diuretics Loop Diuretics BUMETANIDE 100 Burinex Burinex \* Inj 500 mcg per ml, 4 ml vial......7.95 5

▲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

# CARDIOVASCULAR SYSTEM

	Subsidy		Fully Brand or
	(Manufacturer's F	Price) Subs	idised Generic
	\$	Per	<ul> <li>Manufacturer</li> </ul>
FUROSEMIDE [FRUSEMIDE]			
	10.00	1 000	IDCA Environmide
Tab 40 mg – Up to 30 tab available on a PSO		1,000	IPCA-Frusemide
* Tab 500 mg		50	✓ Urex Forte
* Oral liq 10 mg per ml		30 ml OP	<ul> <li>Lasix</li> </ul>
* Inj 10 mg per ml, 25 ml ampoule	60.65	6	<ul> <li>Lasix</li> </ul>
* Inj 10 mg per ml, 2 ml ampoule - Up to 5 inj available on	a PSO2.40	5	<ul> <li>Furosemide-Baxter</li> </ul>
Potassium Sparing Diuretics			
AMILORIDE HYDROCHLORIDE			
Tab 5 mg	81.07	100	Padagis S29
0	171.41	28	✓ Wockhardt S29
Oral liq 1 mg per ml		25 ml OP	✓ Biomed
		25 III OF	♥ Bioliled
EPLERENONE - Special Authority see SA1728 below - Reta	ail pharmacy		
Tab 25 mg		30	<ul> <li>Inspra</li> </ul>
Tab 50 mg		30	✓ Inspra
SA1728 Special Authority for Subsidy			
Initial application from any relevant practitioner. Approvals	alid without further	renewal unless	notified for applications meeting
the following criteria:			
Both:			
1 Patient has heart failure with ejection fraction less than	40%; and		
	140%, anu		
2 Either:			
2.1 Patient is intolerant to optimal dosing of spirono			
2.2 Patient has experienced a clinically significant a	adverse effect while	on optimal dos	sing of spironolactone.
SPIRONOLACTONE			
	0.60	100	Chivactin
* Tab 25 mg		100	<ul> <li>Spiractin</li> </ul>
* Tab 100 mg		100	✓ Spiractin
Oral liq 5 mg per ml	35.70	25 ml OP	<ul> <li>Biomed</li> </ul>
Potassium Sparing Combination Diuretics			
AMILORIDE HYDROCHLORIDE WITH FUROSEMIDE			
* Tab 5 mg with furosemide 40 mg	8.63	28	<ul> <li>Frumil</li> </ul>
AMILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHI	AZIDE		
* Tab 5 mg with hydrochlorothiazide 50 mg		50	✓ Moduretic
		50	• moullelic
Thiazide and Related Diuretics			
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]			
	E1 E0	500	✓ Arrow-
* Tab 2.5 mg – Up to 150 tab available on a PSO		500	
			Bendrofluazide
Marchannes lind on a DOO (amarchan il 11			
May be supplied on a PSO for reasons other than err	• •		<b>4</b> .
* Tab 5 mg	61.00	500	✓ <u>Arrow-</u>
			<b>Bendrofluazide</b>
CHLOROTHIAZIDE			
Oral lig 50 mg per ml	30.67	25 ml OP	<ul> <li>Biomed</li> </ul>
1 61		20 111 01	Diolitica
CHLORTALIDONE [CHLORTHALIDONE]			
			-
* Tab 25 mg	6.95	50	<ul> <li>Hygroton</li> </ul>

	Subsidy	、 、	Fully	Brand or	
	(Manufacturer's Price \$	) Per	Subsidised	Generic Manufacturer	
DAPAMIDE					
• Tab 2.5 mg		90	✓ [	Dapa-Tabs	
ETOLAZONE					
Tab 5 mg	CBS	50	✓ Z	aroxolyn S29	
/asopressin receptor antagonists					
DLVAPTAN – Special Authority see SA2166 below – Re	tail pharmacy				
Tab 15 mg		28 OF	° <b>∕</b> J	linarc	
Tab 30 mg		28 OF	° <b>∕</b> J	linarc	
Tab 45 mg + 15 mg	1,747.00	56 OF	° <b>∕</b> J	linarc	
Tab 60 mg + 30 mg	1,747.00	56 OF	° <b>√</b> J	linarc	
Tab 90 mg + 30 mg	1 747 00	56 OF	> <b>√</b> .	linarc	

#### SA2166 Special Authority for Subsidy

Initial application — (autosomal dominant polycystic kidney disease) only from a renal physician or any relevant practitioner on the recommendation of a renal physician. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 Patient has a confirmed diagnosis of autosomal dominant polycystic kidney disease; and
- 2 Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 25 ml/min/1.73 m<sup>2</sup> at treatment initiation; and
- 3 Fither:
  - 3.1 Patient's disease is rapidly progressing, with a decline in eGFR of greater than or equal to 5 mL/min/1.73 m<sup>2</sup> within one-year; or
  - 3.2 Patient's disease is rapidly progressing, with an average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m<sup>2</sup> per year over a five-year period.

Renewal — (autosomal dominant polycystic kidney disease) only from a renal physician or any relevant practitioner on the recommendation of a renal physician. Approvals valid for 12 months for applications meeting the following criteria: Both:

- 1 Patient has not developed end-stage renal disease, defined as an eGFR of less than 15 mL/min/1.73 m<sup>2</sup>; and
- 2 Patient has not undergone a kidney transplant.

## Lipid-Modifying Agents

### Fibrates

BEZAFIBRATE           * Tab 200 mg         22.65           * Tab long-acting 400 mg         21.54	90 30	<ul> <li>✓ <u>Bezalip</u></li> <li>✓ <u>Bezalip</u> Retard</li> </ul>
Other Lipid-Modifying Agents		
ACIPIMOX * Cap 250 mg	30	<ul> <li>Olbetam</li> </ul>
Resins		
COLESTYRAMINE Powder for oral suspension 4 g sachet61.50	50	<ul> <li>Colestyramine - Mylan 529</li> <li>Quantalan sugar free 529</li> </ul>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
HMG CoA Reductase Inhibitors (Statins)				
ATORVASTATIN				
* Tab 10 mg	0.31	30	✓ L	orstat
ů –	5.16	500	✓ Ī	orstat
* Tab 20 mg	8.12	500	✓ Ī	orstat
* Tab 40 mg		500	✓ 1	orstat
* Tab 80 mg		500	✓ <u>L</u>	orstat
PRAVASTATIN				
* Tab 20 mg		100	✓ (	Clinect
* Tab 40 mg		100		Clinect
ROSUVASTATIN - Special Authority see SA2093 below - Retai			-	
* Tab 5 mg		30	✓ F	Rosuvastatin Viatris
* Tab 10 mg		30	🖌 F	Rosuvastatin Viatris
* Tab 20 mg		30	✓ F	Rosuvastatin Viatris
* Tab 40 mg		30	✓ F	Rosuvastatin Viatris
			-	

### ➡SA2093 Special Authority for Subsidy

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

- 1 Both:
  - 1.1 Patient is considered to be at risk of cardiovascular disease; and
  - 1.2 Patient is Māori or any Pacific ethnicity; or
- 2 Both:
  - 2.1 Patient has a calculated risk of cardiovascular disease of at least 15% over 5 years; and
  - 2.2 LDL cholesterol has not reduced to less than 1.8 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin.

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

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

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

Both:

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

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

Both:

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

		Subsidy		Fully Brand or
		(Manufacturer's Pri	ce) Subs	sidised Generic
		\$	Per	<ul> <li>Manufacturer</li> </ul>
IN/	VASTATIN			
	Tab 10 mg	1.68	90	<ul> <li>Simvastatin Mylan</li> </ul>
•	Tab T0 Hig	1.00	90	✓ Simvastatin Wylan
	T   00	0.54		••••••
-	Tab 20 mg		90	<ul> <li>Simvastatin Viatris</li> </ul>
	Tab 40 mg		90	<ul> <li>Simvastatin Viatris</li> </ul>
÷	Tab 80 mg	8.81	90	<ul> <li>Simvastatin Viatris</li> </ul>
S	elective Cholesterol Absorption Inhibitors			
71	TIMIBE			
	Tab 10 mg	1 76	30	<ul> <li>Ezetimibe Sandoz</li> </ul>
	-	1.70	30	
ZE	ETIMIBE WITH SIMVASTATIN			
	Tab 10 mg with simvastatin 10 mg	5.15	30	<ul> <li>Zimybe</li> </ul>
	Tab 10 mg with simvastatin 20 mg		30	<ul> <li>Zimybe</li> </ul>
	Tab 10 mg with simvastatin 40 mg		30	<ul> <li>Zimybe</li> </ul>
	Tab 10 mg with simvastatin 80 mg		30	✓ Zimybe
			00	
N	itrates			
ίĽ	CERYL TRINITRATE			
ŧ	Oral pump spray, 400 mcg per dose – Up to 250 dose			
	available on a PSO	7 48 2	50 dose OP	<ul> <li>Nitrolingual Pump</li> </ul>
	Database Francisco data	45 70	00	Spray
	Patch 25 mg, 5 mg per day		30	<ul> <li>Nitroderm TTS</li> </ul>
ŧ	Patch 50 mg, 10 mg per day		30	<ul> <li>Nitroderm TTS</li> </ul>
SC	SORBIDE MONONITRATE			
	Tab 20 mg	22 49	100	🗸 Ismo 20
	Tab long-acting 40 mg		30	✓ Ismo 40 Retard
	0 0 0			
ĸ	Tab long-acting 60 mg		90	✓ <u>Duride</u>
S	ympathomimetics			
J	Inpatronimetics			
D	RENALINE			
	Inj 1 in 1,000, 1 ml ampoule - Up to 5 inj available on a PSO	4.98	5	<ul> <li>Aspen Adrenaline</li> </ul>
		13.27		DBL Adrenaline
		25.30	10	✓ Hameln S29
	Ini 1 in 10,000, 10 ml amnaula — Lin ta E ini available an a DC			
	Inj 1 in 10,000, 10 ml ampoule – Up to 5 inj available on a PS		5	<ul> <li>Hospira</li> </ul>
		49.00	10	<ul> <li>Aspen Adrenaline</li> </ul>
la	meln S29 Inj 1 in 1,000, 1 ml ampoule to be delisted 1 Octob	er 2025)		
.,				
V	asodilators			
ΙY	DRALAZINE HYDROCHLORIDE			
	Tab 25 mg – Special Authority see SA1321 on the next page	_		
	Retail pharmacy	CBS	1	<ul> <li>Hydralazine</li> </ul>
			56	<ul> <li>Onelink S29</li> </ul>
			84	✓ AMDIPHARM \$29
			100	✓ Camber S29
			100	
	Inj 20 mg ampoule	05.00	5	<ul> <li>Apresoline</li> </ul>

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

### ⇒SA1321 Special Authority for Subsidy

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

Either:

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

#### MINOXIDIL

▲ Tab 10 mg	47.04	60	<ul> <li>Minoxidil Roma S29</li> </ul>
	78.40	100	<ul> <li>Loniten</li> </ul>
NICORANDIL			
▲ Tab 10 mg	21.73	60	<ul> <li>Max Health</li> </ul>
▲ Tab 20 mg		60	<ul> <li>Max Health</li> </ul>
PAPAVERINE HYDROCHLORIDE			
* Inj 12 mg per ml, 10 ml ampoule	257.12	5	<ul> <li>Hospira</li> </ul>
PENTOXIFYLLINE [OXPENTIFYLLINE]			
Tab 400 mg	44.37	50	<ul> <li>Trental 400</li> </ul>
Endothelin Receptor Antagonists			

### Endothelin Receptor Antagonists

AMBRISENTAN – Special Authority see SA2486 below – Retail pharmacy		
Tab 5 mg	30	<ul> <li>Ambrisentan Viatris</li> </ul>
Tab 10 mg200.00	30	✓ Ambrisentan Viatris

### ⇒SA2486 Special Authority for Subsidy

**Initial application** — (**PAH monotherapy**) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH 2022 (see note below for link to these guidelines) †; or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or

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

- developmental lung disorders including chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
  - 5.1 Ambrisentan is to be used as PAH monotherapy; and
  - 5.2 Any of the following:
    - 5.2.1 Patient has experienced intolerable side effects with both sildenafil and bosentan; or
    - 5.2.2 Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
    - 5.2.3 Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease.

**Initial application** — (PAH dual therapy) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>-5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH 2022 (see note below for link to these guidelines) †; or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
  - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
  - 5.1 Ambrisentan is to be used as PAH dual therapy; and
  - 5.2 Any of the following:
    - 5.2.1 Patient has tried bosentan (either as PAH monotherapy, or PAH dual therapy with sildenafil) for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool\*\*; or
    - 5.2.2 Patient has experienced intolerable side effects on bosentan; or
    - 5.2.3 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
    - 5.2.4 Patient is presenting in NYHA/WHO functional class III or IV, and would benefit from initial dual therapy in the opinion of the treating clinician and has an absolute or relative contraindication to bosentan (eg. due to current liver disease or use of a combined oral contraceptive).

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

**Initial application** — (PAH triple therapy) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH 2022 (see note below for link to these guidelines) †; or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
  - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
  - 5.1 Ambrisentan is to be used as PAH triple therapy; and
  - 5.2 Any of the following:
    - 5.2.1 Patient is on the lung transplant list; or
    - 5.2.2 Both:
      - 5.2.2.1 Patient is presenting in NYHA/WHO functional class IV; and
      - 5.2.2.2 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or

#### 5.2.3 Both:

- 5.2.3.1 Patient has tried PAH dual therapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool\*\*; and
- 5.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

**Renewal** only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years where the patient is continuing to derive benefit from ambrisentan treatment according to a validated PAH risk stratification tool\*\*.

Notes: † The European Respiratory Journal Guidelines can be found here: <u>2022 ECS/ERS Guidelines for the diagnosis and</u> treatment of pulmonary hypertension PAH

\*\* the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
BOSENTAN - Special Authority see SA2254 below - Retail pha	rmacy				
Tab 62.5 mg	100.00	60	✓ [	Bosentan Dr	
				Reddy's	
Tab 125 mg	100.00	60	✓ [	Bosentan Dr	
				Reddy's	

## ► SA2254 Special Authority for Subsidy

**Initial application** — (PAH monotherapy) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
  - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
  - 5.1 Bosentan is to be used as PAH monotherapy; and
  - 5.2 Any of the following:
    - 5.2.1 Patient has experienced intolerable side effects on sildenafil; or
    - 5.2.2 Patient has an absolute contraindication to sildenafil; or
    - 5.2.3 Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease.

**Initial application** — (PAH dual therapy) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and

Subsidy	F	ully	Brand or	
(Manufacturer's Price)	Subsidis	sed	Generic	
\$	Per	✓	Manufacturer	

- 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
- 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
- 4.1.5 Any of the following:
  - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
  - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
  - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Bosentan is to be used as part of PAH dual therapy; and

6 Either:

- 6.1 Patient has tried a PAH monotherapy (sildenafil) for at least three months and has experienced an inadequate therapeutic response to treatment according to a validated risk stratification tool\*\*; or
- 6.2 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would likely benefit from initial dual therapy.

**Initial application — (PAH triple therapy)** only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
  - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and

5 Both:

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5.1 Bosentan is to be used as part of PAH triple therapy; and

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

- 5.2 Any of the following:
  - 5.2.1 Patient is on the lung transplant list; or
  - 5.2.2 Patient is presenting in NYHA/WHO functional class IV; or
  - 5.2.3 Both:
    - 5.2.3.1 Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool\*\*; and
    - 5.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

**Renewal** only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years where patient is continuing to derive benefit from bosentan treatment according to a validated PAH risk stratification tool\*\*.

Notes: † The European Respiratory Journal Guidelines can be found here: <u>2022 ECS/ERS Guidelines for the diagnosis and</u> treatment of pulmonary hypertension PAH

\*\* the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

## Phosphodiesterase Type 5 Inhibitors

SILDENAFIL – Special Authority see SA2255 below – Retail pharmacy		
Tab 25 mg0.72	4	<ul> <li>Vedafil</li> </ul>
Tab 50 mg1.45	4	<ul> <li>Vedafil</li> </ul>
Tab 100 mg11.22	12	<ul> <li>Vedafil</li> </ul>

### ⇒SA2255 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, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria: All of the following:

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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH is confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) of greater than 20 mmHg; and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) that is less than or equal to 15 mmHg; and
    - 4.1.4 Pulmonary vascular resistance (PVR) of at least 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and

▲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	Fu	ly Brand or	
(Manufacturer's Price)	Subsidise	d Generic	
\$	Per	<ul> <li>Manufacturer</li> </ul>	

- 4.1.5 Any of the following:
  - 4.1.5.1 PAH is non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
  - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
  - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures.

**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.

Notes: Note: Indications marked with \* are Unapproved Indications.

† The European Respiratory Journal Guidelines can be found here: <u>2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH</u>

\*\* the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

### **Prostacyclin Analogues**

EPOPROSTENOL - Special Authority see SA2256 belo	ow – Retail pharmacy		
Inj 500 mcg vial		1	🗸 Veletri
Inj 1.5 mg vial	73.21	1	🗸 Veletri

### ⇒SA2256 Special Authority for Subsidy

**Initial application** — (PAH dual therapy) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these

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

continued...

guidelines) † ; or

- 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
- 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 All of the following:
  - 5.1 Epoprostenol is to be used as part of PAH dual therapy with either sildenafil or an endothelin receptor antagonist; and
  - 5.2 Patient is presenting in NYHA/WHO functional class IV; and
  - 5.3 Patient has tried a PAH monotherapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool.

**Initial application — (PAH triple therapy)** only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
  - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
  - 5.1 Epoprostenol is to be used as PAH triple therapy; and
  - 5.2 Any of the following:
    - 5.2.1 Patient is on the lung transplant list; or
    - 5.2.2 Patient is presenting in NYHA/WHO functional class IV; or
    - 5.2.3 Both:
      - 5.2.3.1 Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool; and

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

5.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

**Renewal** only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years where patient is continuing to derive benefit from epoprostenol treatment according to a validated PAH risk stratification tool\*\*.

Notes: † The European Respiratory Journal Guidelines can be found here: <u>2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH</u>

\*\* the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

ILOPROST – Special Authority see SA2257 below – Retail pharmacy

Nebuliser soln 10 mcg per ml, 2 ml ..... 166.53

⇒SA2257 Special Authority for Subsidy

**Initial application** — (PAH monotherapy) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:

### 4.1 All of the following:

- 4.1.1 PAH has been confirmed by right heart catheterisation; and
- 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
- 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
- 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
- 4.1.5 Any of the following:
  - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
  - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
  - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:

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- 5.1 Iloprost is to be used as PAH monotherapy; and
- 5.2 Either:
  - 5.2.1 Patient has experienced intolerable side effects on sildenafil and both the funded endothelin receptor antagonists (i.e. both bosentan and ambrisentan); or
  - 5.2.2 Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to endothelin receptor antagonists.

**Initial application** — (PAH dual therapy) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months for

continued...

✓ Vebulis

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

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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II. III or IV: and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>-5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these auidelines) + : or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease: or
  - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures ; and
- 5 All of the following:
  - 5.1 lloprost is to be used as PAH dual therapy with either sildenafil or an endothelin receptor antagonist; and 5.2 Fither:
  - - 5.2.1 Patient has an absolute contraindication to or has experienced intolerable side effects on sildenafil: or
    - 5.2.2 Patient has an absolute or relative contraindication to or experienced intolerable side effects with a funded endothelin receptor antagonist; and
  - 5.3 Either:
    - 5.3.1 Patient has tried a PAH monotherapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool\*\*; or
    - 5.3.2 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would benefit from initial dual therapy.

Initial application — (PAH triple therapy) only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. 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 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II. III or IV: and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and

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

- 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
- 4.1.5 Any of the following:
  - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
  - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
  - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and

### 5 Both:

- 5.1 Iloprost is to be used as PAH triple therapy; and
- 5.2 Any of the following:
  - 5.2.1 Patient is on the lung transplant list; or
  - 5.2.2 Patient is presenting in NYHA/WHO functional class IV; or
  - 5.2.3 Both:
    - 5.2.3.1 Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool\*\*; and
    - 5.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

**Renewal** only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years where patient is continuing to derive benefit from iloprost treatment according to a validated PAH risk stratification tool\*\*.

Notes: † The European Respiratory Journal Guidelines can be found here: <u>2022 ECS/ERS Guidelines for the diagnosis and</u> treatment of pulmonary hypertension PAH

\*\* the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

	Subsidy		Fully	Brand or
	(Manufacturer's Price)			Generic
	\$	Per	/	Manufacturer
Antiacne Preparations				
For systemic antibacterials, refer to INFECTIONS, Antibacterials,	page 95			
ADAPALENE				
a) Maximum of 30 g per prescription				
b) Only on a prescription				
Gel 0.1%		80 g OP	🗸 D	ifferin
ISOTRETINOIN - Special Authority see SA2449 below - Retail p	harmacy			
Cap 5 mg		60	✓ 0	ratane
Cap 10 mg		120	✓ 0	ratane
Cap 20 mg		120	✓ 0	ratane

### ➡SA2449 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, paediatrician, 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 Any of the following:

- 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; or
- 3.3 Patient is a child and it is considered not appropriate to exclude pregnancy or start contraceptives or undertake pregnancy-related isotretinoin counselling.

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

- 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; or
- 3 Patient is a child and it is considered not appropriate to exclude pregnancy or start contraceptives or undertake pregnancy-related isotretinoin counselling.

Crm 0.5 mg per g – Maximum of 50 g per prescription	16.82	50 g OP	✓ <u>ReTrieve</u>
Antibacterials Topical			
For systemic antibacterials, refer to INFECTIONS, Antibacterials, pa	ge 95		
HYDROGEN PEROXIDE			
* Crm 1%	8.56	10 g OP	<ul> <li>Crystaderm</li> </ul>
MUPIROCIN			
Oint 2%		15 g OP	
	(13.00)		Bactroban
<ul> <li>a) Only on a prescription</li> </ul>			
<li>b) Not in combination</li>			

	Subsidy (Manufacturer's F \$	Price) Subs Per	Fully Brand or idised Generic ✓ Manufacturer	
SODIUM FUSIDATE [FUSIDIC ACID]	Ŷ	1.61		
Crm 2%	1.69	5 g OP	<ul> <li>Foban</li> </ul>	
a) Maximum of 5 g per prescription		0		
b) Only on a prescription				
c) Not in combination Oint 2%	1 69	5 g OP	<ul> <li>Foban</li> </ul>	
a) Maximum of 5 g per prescription		5 y 01		
b) Only on a prescription				
c) Not in combination				
SULFADIAZINE SILVER	40.00			
Crm 1%		50 g OP	<ul> <li>Flamazine</li> </ul>	
<ul><li>a) Up to 250 g available on a PSO</li><li>b) Not in combination</li></ul>				
Antifungals Topical				
For systemic antifungals, refer to INFECTIONS, Antifungals,	bage 103			
AMOROLFINE				
<ul> <li>a) Only on a prescription</li> <li>b) Not in combination</li> </ul>				
Nail soln 5%		5 ml OP	✓ MycoNail	
CLOTRIMAZOLE				
* Crm 1%	1.10	20 g OP	<ul> <li>Clomazol</li> </ul>	
a) Only on a prescription				
b) Not in combination	4.00	20 ml OP		
* Soln 1%	4.36 (7.55)	20 MI OP	Canesten	
a) Only on a prescription	(1.00)		Callocton	
b) Not in combination				
ECONAZOLE NITRATE				
Crm 1%	8.04	20 g OP	<ul> <li>Pevaryl</li> </ul>	
<ul><li>a) Only on a prescription</li><li>b) Not in combination</li></ul>				
Foaming soln 1%, 10 ml sachets		3		
	(18.64)		Pevaryl	
a) Only on a prescription				
b) Not in combination				
	0.00	15 a OB	Multicham	
<ul> <li>Crm 2%a) Only on a prescription</li> </ul>	0.90	15 g OP	<ul> <li><u>Multichem</u></li> </ul>	
b) Not in combination				
* Lotn 2%	4.36	30 ml OP		
	(10.03)		Daktarin	
<ul><li>a) Only on a prescription</li><li>b) Not in combination</li></ul>				
<ul> <li>b) Not in combination</li> <li>* Tinct 2%</li> </ul>		30 ml OP		
	(12.10)		Daktarin	
a) Only on a prescription	. ,			
b) Not in combination				

## DERMATOLOGICALS

	Subsidy		Fully Brand or	
	(Manufacturer's F		sidised Generic	
	\$	Per	Manufacturer	
Antipruritic Preparations				
ALAMINE				
a) Only on a prescription				
b) Not in combination				
Crm, aqueous, BP	3.45	100 g	<ul> <li>healthE Calamine</li> </ul>	
			Aqueous	
ROTAMITON				
<ul><li>a) Only on a prescription</li><li>b) Not in combination</li></ul>				
Crm 10%	3.49	20 g OP	✓ Itch-Soothe	
IENTHOL – Only in combination		20 9 01		
<ol> <li>Only in combination with a dermatological base or propri</li> </ol>	iatary Tonical C	orticostariad	Plain	
2) With or without other dermatological galenicals.	icialy i upical C			
Crystals	6.92	25 g	✓ MidWest	
-	29.60	100 g	✓ MidWest	
Cortigostoroids Topical				
Corticosteroids Topical				
or systemic corticosteroids, refer to CORTICOSTEROIDS AND F	RELATED AGE	NTS, page 84		
Corticosteroids - Plain				
ETAMETHASONE DIPROPIONATE			_	
Crm 0.05%		15 g OP	<ul> <li>Diprosone</li> </ul>	
•••••	36.00	50 g OP	<ul> <li><u>Diprosone</u></li> </ul>	
Oint 0.05%	2.96	15 g OP	<ul> <li>Diprosone</li> </ul>	
	2.96 36.00	15 g OP 50 g OP	<ul> <li>Diprosone</li> <li>Diprosone</li> </ul>	
Oint 0.05% in propylene glycol base	2.96 36.00	15 g OP	<ul> <li>Diprosone</li> </ul>	
Oint 0.05% in propylene glycol base ETAMETHASONE VALERATE	2.96 36.00 4.33	15 g OP 50 g OP 30 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li>Diprosone OV</li> </ul>	
Oint 0.05% in propylene glycol base ETAMETHASONE VALERATE € Crm 0.1%	2.96 36.00 4.33	15 g OP 50 g OP 30 g OP 50 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li>Diprosone OV</li> <li><u>Beta Cream</u></li> </ul>	
Oint 0.05% in propylene glycol base ETAMETHASONE VALERATE € Crm 0.1% € Oint 0.1%	2.96 36.00 4.33 5.85 7.90	15 g OP 50 g OP 30 g OP 50 g OP 50 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li>Diprosone OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> </ul>	
Oint 0.05% in propylene glycol base ETAMETHASONE VALERATE € Crm 0.1%	2.96 36.00 4.33 5.85 7.90	15 g OP 50 g OP 30 g OP 50 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li>Diprosone OV</li> <li><u>Beta Cream</u></li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE           € Crm 0.1%           € Oint 0.1%           € Lotn 0.1%           LOBETASOL PROPIONATE		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li>Diprosone OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> </ul>	
Oint 0.05% in propylene glycol base ETAMETHASONE VALERATE © Crm 0.1% © Oint 0.1% © Lotn 0.1%		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li><u>Dermol</u></li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE           € Crm 0.1%           € Oint 0.1%           € Lotn 0.1%           LOBETASOL PROPIONATE	2.96 36.00 4.33 5.85 7.90 30.00 2.40	15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li>Diprosone OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE           € Crm 0.1%           € Oint 0.1%           € Lotn 0.1%           LOBETASOL PROPIONATE           € Crm 0.05%	2.96 36.00 4.33 5.85 7.90 30.00 2.40	15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li><u>Dermol</u></li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li><u>Dermol</u></li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE           € Crm 0.1%           € Oint 0.1%           € Lotn 0.1%           LOBETASOL PROPIONATE           € Crm 0.05%           € Oint 0.05%           LOBETASONE BUTYRATE		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP 30 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li><u>Dermol</u></li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE           € Crm 0.1%           € Oint 0.1%           € Lotn 0.1%           LOBETASOL PROPIONATE           € Crm 0.05%           € Oint 0.05%           LOBETASONE BUTYRATE		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP 30 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li>Dermol</li> <li>Dermol</li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE           € Crm 0.1%           € Oint 0.1%           € Lotn 0.1%           LOBETASOL PROPIONATE           € Crm 0.05%           € Oint 0.05%           LOBETASONE BUTYRATE           Crm 0.05%           YDROCORTISONE		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP 30 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li>Dermol</li> <li>Dermol</li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE <ul></ul>		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP 30 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li>Dermol</li> <li>Dermol</li> <li>Eumovate</li> </ul>	
Oint 0.05% in propylene glycol base           ETAMETHASONE VALERATE           € Crm 0.1%           € Oint 0.1%           € Lotn 0.1%           LOBETASOL PROPIONATE           € Crm 0.05%           € Oint 0.05%           LOBETASONE BUTYRATE           Crm 0.05%           YDROCORTISONE		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP 30 g OP 30 g OP	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li><u>Dermol</u></li> <li><u>Dermol</u></li> <li><u>Eumovate</u></li> <li><u>Eumovate</u></li> <li><u>Ethics</u></li> </ul>	
Oint 0.05% in propylene glycol base         ETAMETHASONE VALERATE <ul> <li>Crm 0.1%</li> <li>Oint 0.1%</li> <li>Lotn 0.1%</li> <li>LOBETASOL PROPIONATE</li> <li>Crm 0.05%</li> <li>Oint 0.05%</li> </ul> LOBETASONE BUTYRATE Crm 0.05%         VDBETASONE BUTYRATE Crm 0.05%         YDROCORTISONE <ul> <li>Crm 1% – Only on a prescription</li> </ul>		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP 30 g OP 30 g OP 30 g OP 30 g OP 500 g 25 g	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li><u>Dermol</u></li> <li>Dermol</li> <li><u>Dermol</u></li> <li>Eumovate</li> <li><u>Ethics</u></li> <li>Noumed</li> <li>ABM</li> </ul>	
Oint 0.05% in propylene glycol base ETAMETHASONE VALERATE © Crm 0.1% © Lotn 0.1% © LOBETASOL PROPIONATE © Crm 0.05% © Oint 0.05% © Oint 0.05% © LOBETASONE BUTYRATE Crm 0.05% POROCORTISONE © Crm 1% - Only on a prescription © Powder - Only in combination		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP 30 g OP 30 g OP 30 g OP 30 g OP 500 g 25 g	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li><u>Dermol</u></li> <li>Dermol</li> <li><u>Dermol</u></li> <li>Eumovate</li> <li><u>Ethics</u></li> <li>Noumed</li> <li>ABM</li> </ul>	
Oint 0.05% in propylene glycol base         ETAMETHASONE VALERATE         € Crm 0.1%         € Oint 0.1%         € Lotn 0.1%         LOBETASOL PROPIONATE         € Crm 0.05%         COBETASONE BUTYRATE         Crm 0.05%         LOBETASONE BUTYRATE         Crm 0.05%         YDROCORTISONE         € Crm 1% - Only on a prescription         € Powder - Only in combination         Up to 5% in a dermatological base (not proprietary Topica galenicals		15 g OP 50 g OP 30 g OP 50 g OP 50 g OP 50 ml OP 30 g OP 30 g OP 30 g OP 30 g OP 30 g OP 500 g 25 g	<ul> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u></li> <li><u>Diprosone</u> OV</li> <li><u>Beta Cream</u></li> <li><u>Beta Ointment</u></li> <li><u>Betnovate</u></li> <li><u>Dermol</u></li> <li>Dermol</li> <li><u>Dermol</u></li> <li>Eumovate</li> <li><u>Ethics</u></li> <li>Noumed</li> <li>ABM</li> </ul>	

▲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

## DERMATOLOGICALS

	Subsidy		Fully Brand or
	(Manufacturer's F		idised Generic
	\$	Per	<ul> <li>Manufacturer</li> </ul>
IYDROCORTISONE BUTYRATE	4.05	100 00	
Lipocream 0.1%		100 g OP	<ul> <li>Locoid Lipocream</li> </ul>
Oint 0.1%		100 g OP	✓ Locoid
Milky emul 0.1%		100 ml OP	<ul> <li>Locoid Crelo</li> </ul>
IETHYLPREDNISOLONE ACEPONATE			<b>.</b>
Crm 0.1%		15 g OP	Advantan
Oint 0.1%	4.95	15 g OP	✓ Advantan
IOMETASONE FUROATE			
Crm 0.1%		15 g OP	Elocon Alcohol Free
••••••	3.50	50 g OP	Elocon Alcohol Free
Oint 0.1%		15 g OP	Elocon
	3.50	50 g OP	<ul> <li>Elocon</li> </ul>
Lotn 0.1%	4.99	30 ml OP	Elocon
RIAMCINOLONE ACETONIDE			
Crm 0.02%		100 g OP	✓ Aristocort
Oint 0.02%	6.54	100 g OP	<ul> <li>Aristocort</li> </ul>
Corticosteroids - Combination			
BETAMETHASONE VALERATE WITH SODIUM FUSIDATE [F			
Crm 0.1% with sodium fusidate (fusidic acid) 2%		15 g OP	
	(10.45)	10 9 01	Fucicort
a) Maximum of 15 g per prescription	(*****)		
b) Only on a prescription			
	intion		
HYDROCORTISONE WITH MICONAZOLE – Only on a prescr ₭ Crm 1% with miconazole nitrate 2%		15 a OB	Mioromo H
		15 g OP	Micreme H
IYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN – Oint 1% with natamycin 1% and neomycin sulphate 0.5%	, , ,	otion 15 g OP	✓ Pimafucort
RIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMY		-	
Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 r		15 a OB	
and gramicidin 250 mcg per g – Only on a prescription		15 g OP	Viaderm KC
	(9.28)		Viauenni KC
Barrier Creams and Emollients			
Barrier Creams			
DIMETHICONE			<b>.</b>
Crm 5% pump bottle	4.30	460 g OP	<ul> <li>healthE</li> </ul>
			Dimethicone 5%
Crm 10% pump bottle	4.52	460 g OP	<ul> <li>healthE</li> </ul>
			Dimethicone 10%
INC AND CASTOR OIL			
₭ Oint	4.25	500 g	<ul> <li>Evara</li> </ul>
Emollients			
QUEOUS CREAM			
€ Crm	1.65	500 g	✓ Evara
		000 g	<u>= 1414</u>
	0.00	500 ~	<ul> <li>Cetomacrogol-AFT</li> </ul>
₭ Crm BP	2.29	500 g	<ul> <li>Celomacrogol-AFT</li> </ul>
✓ fully subsidised	S29 Unapr	proved medicine a	supplied under Section 29
70 Principal Supply		dised Supply	Supplied and of Ocolion 20

Principal Supply

## DERMATOLOGICALS

	Subsidy		Fully Brand or
	(Manufacturer's	Price) Subs	idised Generic
	\$	Per	<ul> <li>Manufacturer</li> </ul>
CETOMACROGOL WITH GLYCEROL			
Crm 90% with glycerol 10%	1.92	460 g OP	🗸 Evara
	3.25	920 g OP	🗸 Evara
EMULSIFYING OINTMENT		-	
* Oint BP	3.13	500 g	<ul> <li>Emulsifying</li> </ul>
			Ointment ADE
OIL IN WATER EMULSION			<u></u>
* Crm	2 10	500 g	<ul> <li>Fatty Emulsion</li> </ul>
	2.10	500 g	Cream (Evara)
PARAFFIN	4.04	500 ~ OD	White Coft Linuid
Oint liquid paraffin 50% with white soft paraffin 50%	4.94	500 g OP	✓ White Soft Liquid
			Paraffin AFT
UREA			<b>.</b>
* Crm 10%	1.37	100 g OP	healthE Urea Cream
WOOL FAT WITH MINERAL OIL - Only on a prescription			
* Lotn hydrous 3% with mineral oil	5.60	1,000 ml	
	(14.96)		DP Lotion
	(20.53)		Alpha-Keri Lotion
	1.40	250 ml OP	
	(5.87)		DP Lotion
	5.60	1,000 ml	
	(23.91)		BK Lotion
	1.40	250 ml OP	
	(7.73)		BK Lotion
Other Dermatological Bases			
Other Dermatological Dases			
PARAFFIN			
White soft – Only in combination	4.74	450 g	<ul> <li>EVARA White Soft</li> </ul>
			Paraffin
	19.00	2,500 g	<ul> <li>EVARA White Soft</li> </ul>
			Paraffin Paraffin
Only in combination with a dermatological galenical or	as a diluent for a	proprietary Top	ical Corticosteroid – Plain.
Minor Olin Infontions			
Minor Skin Infections			
POVIDONE IODINE			
Oint 10%	7.40	65 g OP	<ul> <li>Betadine</li> </ul>
a) Maximum of 130 g per prescription		-	
b) Only on a prescription			
Antiseptic Solution 10%	4.99	100 ml	<ul> <li>Riodine</li> </ul>
Antiseptic soln 10%		15 ml	✓ Riodine
	6.99	500 ml	✓ Riodine
Skin preparation, povidone iodine 10% with 30% alcohol	1.63	100 ml	
	(3.48)		Betadine Skin Prep
Parasiticidal Preparations			
Parasiticidal Preparations DIMETHICONE * Lotn 4%	4.25	200 ml OP	✓ healthE
DIMETHICONE	4.25	200 ml OP	✓ healthE Dimethicone 4%

A 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) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer
VERMECTIN – Special Authority see SA2294 below – Retail ph Tab 3 mg – Up to 100 tab available on a PSO		4	✓ s	tromectol
<ol> <li>PSO for institutional use only. Must be endorsed v a valid Special Authority for patient of that institutio</li> <li>Ivermectin available on BSO provided the BSO inc</li> <li>For the purposes of subsidy of ivermectin, institution facilities or prisons.</li> </ol>	n. ludes a valid Special .	Authorit	y for a pa	tient of the institution.
→SA2294 Special Authority for Subsidy nitial application — (Scabies) from any relevant practitioner. priteria: Either:			or applica	tions meeting the followin
<ol> <li>The person has a severe scables hyperinfestation (Cruste</li> <li>Both:</li> </ol>	d/ Norwegian scables	s); or		
<ul><li>2.1 The person has a confirmed diagnosis of scabies of 2.2 Either:</li></ul>	or is a close contact o	f a scab	ies case;	and
2.2.1 The person is unable to complete topical th 2.2.2 Previous treatment with topical therapy has		oorod th	o infaata	lion
nitial application — (Other parasitic infections) from any rele neeting the following criteria:				
Any of the following:				
1 filariasis; or				
2 cutaneous larva migrans (creeping eruption); or				
3 strongyloidiasis. Renewal — (Scabies) from any relevant practitioner. Approvals	valid for 1 month for	annlica	tions mad	ting the following criteria
Either:		applica		ang the following chiena
1 The person has a severe scabies hyperinfestation (Cruste 2 Both:	d/ Norwegian scabies	s); or		
2.1 The person has a confirmed diagnosis of scabies of 2.2 Either:	or is a close contact o	f a scab	ies case;	and
2.2.1 The person is unable to complete topical th				
2.2.2 Previous treatment with topical therapy has				
Renewal — (Other parasitic infections) from any relevant pract following criteria:	titioner. Approvals va	alid for 1	month to	or applications meeting th
Any of the following:				
1 filariasis; or				
2 cutaneous larva migrans (creeping eruption); or				
3 strongyloidiasis.				
PERMETHRIN				<b>•</b> • •
Lotn 5%		ml OP	✓ A	-Scabies

ACITRETIN - Special Authority see SA2024 on the next page - Reta	ail pharmacy		
Cap 10 mg	26.20	60	<ul> <li>Novatretin</li> </ul>
Cap 25 mg	57.37	60	✓ Novatretin

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

#### ➡SA2024 Special Authority for Subsidy

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

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

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

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

#### BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL

Foam spray 500 mcg with calcipotriol 50 mcg per g       59.95         Gel 500 mcg with calcipotriol 50 mcg per g       40.92         Oint 500 mcg with calcipotriol 50 mcg per g       14.31	60 g OP 60 g OP 30 g OP	<ul> <li>Enstilar</li> <li>Daivobet</li> <li>Daivobet</li> </ul>
CALCIPOTRIOL Oint 50 mcg per g40.00	120 g OP	<ul> <li>Daivonex</li> </ul>
COAL TAR Soln BP – Only in combination	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.

#### COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR

Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% an	d		
allantoin crm 2.5%	6.59	75 g OP	
	(8.00)	-	Egopsoryl TA
	3.43	30 g OP	0, ,
	(4.35)	5	Egopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR			
Soln 12% with salicylic acid 2% and sulphur 4% oint	7.95	40 g OP	<ul> <li>Coco-Scalp</li> </ul>
PIMECROLIMUS - Special Authority see SA1970 below - Retai	l pharmacy		
a) Maximum of 15 g per prescription			
b) Note: a maximum of 15 g per prescription and no more t	han one prescrip	tion per 12 we	eks.
Cream 1%		15 g OP	<ul> <li>Elidel</li> </ul>
SA1970 Special Authority for Subsidy			

#### ⇒SA1970 Special Authority for Subsidy

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

	Subsidy		Full	y Brand or
	(Manufacturer's Pi \$	rice) Per	Subsidise	,
continued neeting the following criteria: Both:				
<ol> <li>Patient has atopic dermatitis on the eyelid; and</li> <li>Patient has at least one of the following contraindications documented epidermal atrophy, documented allergy to to pressure.</li> </ol>				
PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORE Soln 2.3% with trolamine laurilsulfate and fluorescein sodium		n a presc 500 r	•	Pinetarsol
SALICYLIC ACID Powder – Only in combination		250	g 🗸	<b>Midwest</b>
<ol> <li>Only in combination with a dermatological base or</li> <li>With or without other dermatological galenicals.</li> </ol>	proprietary Topic	al Cortico	osteroid –	Plain or collodion flexible
SULPHUR Precipitated – Only in combination	6.35	100	a 🗸	Midwest
<ol> <li>Only in combination with a dermatological base or</li> <li>With or without other dermatological galenicals.</li> </ol>			•	Plain
ACROLIMUS				
Oint 0.1% – Special Authority see SA2074 below – Retail pharmacy		30 g C	DP 🗸	Zematop
<ul><li>a) Maximum of 30 g per prescription</li><li>b) Note: a maximum of 30 g per prescription and no m</li></ul>	ore than one pres	cription p	per 12 wee	eks.
SA2074 Special Authority for Subsidy nitial application only from a dermatologist, paediatrician or an vaediatrician, . Approvals valid without further renewal unless no soft:				
<ol> <li>Patient has atopic dermatitis on the face; and</li> <li>Patient has at least one of the following contraindications documented epidermal atrophy or documented allergy to</li> </ol>			periorificia	al dermatitis, rosacea,
Scalp Preparations				
BETAMETHASONE VALERATE	10.05	100	0.0	
₭ Scalp app 0.1% CLOBETASOL PROPIONATE		100 ml	00	Beta Scalp
✤ Scalp app 0.05% IYDROCORTISONE BUTYRATE	6.26	30 ml (	OP 🗸	Dermol
Scalp lotn 0.1%	6.57	100 ml	OP 🗸	Locoid
KETOCONAZOLE Shampoo 2%		100 ml	-	Sebizole
<ul><li>a) Maximum of 100 ml per prescription</li><li>b) Only on a prescription</li></ul>	4.09		Ū	<u>Sebizole</u>

#### Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per Manufacturer 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. 200 g OP ✓ Marine Blue Lotion SPF 50+ Wart Preparations For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 72 PODOPHYLLOTOXIN 3.5 ml OP Condyline a) Maximum of 3.5 ml per prescription b) Only on a prescription **Other Skin Preparations** Antineoplastics FLUOROURACIL SODIUM 20 g OP Efudix IMIQUIMOD Crm 5%, 250 mg sachet......21.72 24 Perrigo

DERMATOLOGICALS

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

#### Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per Manufacturer **Contraceptives - Non-hormonal** Condoms CONDOMS \* 49 mm - Up to 144 dev available on a PSO ...... 14.25 ✓ Moments 144 Moments 10 Moments 14 25 144 a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO 10 ✓ Moments \* ✓ Moments 14.25 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription ✓ Moments 10 Moments 14.25 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription 53 mm, strawberry, red.....1.15 ✓ Moments \* 10 14.25 144 ✓ Moments a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription Moments 10 14.50 144 ✓ Moments a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO \* 56 mm. 0.05 mm thickness......2.00 Gold Knight 12 Gold Knight 24.10 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription 144 Gold Knight a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO ✓ Moments 10 \* ✓ Moments 14.25 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription ✓ Moments 10 14.25 144 Moments a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription Gold Knight 12 Gold Knight 21.45 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription Gold Knight 12 21.45 144 Gold Knight a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription 12 Gold Knight XL 21.89 144 Gold Knight XL a) Maximum of 60 dev per prescription

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### **GENITO-URINARY SYSTEM**

# **GENITO-URINARY SYSTEM**

	Subsidy (Manufacturer's Price) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer
<ul><li>a) Maximum of 60 dev per prescription</li><li>b) Up to 60 dev available on a PSO</li></ul>				
Contraceptive Devices				
INTRA-UTERINE DEVICE a) Up to 40 dev available on a PSO b) Only on a PSO				
<ul> <li>* IUD 29.1 mm length × 23.2 mm width</li> </ul>	29.80	1	·	hoice 380 7med Nsha Silver/ copper Short
* IUD 33.6 mm length × 29.9 mm width		1		Cu 380 Plus Normal
* IUD 35.5 mm length × 19.6 mm width		1	✓ C	u 375 Standard

# **Contraceptives - Hormonal**

#### **Combined Oral Contraceptives**

#### ⇒SA0500 Special Authority for Alternate Subsidy

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

1 Either:

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

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

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

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

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

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

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

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

#### ETHINYLOESTRADIOL WITH DESOGESTREL

*	Tab 20 mcg with desogestrel 150 mcg and 7 inert tab - Up	o to		
	84 tab available on a PSO		84	<ul> <li>Mercilon 28</li> </ul>

### **GENITO-URINARY SYSTEM**

	Subsidy (Manufacturer's Price) \$	Su Per	Fully Ibsidised	Brand or Generic Manufacturer
ETHINYLOESTRADIOL WITH LEVONORGESTREL	Ŷ			inanalaolaroi
* Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets	-			
Up to 84 tab available on a PSO		84	✓ L	o-Oralcon 20 ED
* Tab 30 mcg with levonorgestrel 150 mcg	6.62	63		
	(16.50)		N	licrogynon 30
<ul> <li>a) Higher subsidy of \$15.00 per 63 tab with Special Aut</li> <li>b) Up to 63 tab available on a PSO</li> <li>* Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets Up to 84 tab available on a PSO</li> </ul>	-	the pre		ralcon 30 ED
ETHINYLOESTRADIOL WITH NORETHISTERONE Tab 35 mcg with norethisterone 1 mg and 7 inert tab – Up to 84 tab available on a PSO		84		lyacen revinor 1/28
Tab 35 mcg with norethisterone 500 mcg and 7 inert tab – L to 84 tab available on a PSO		84	🗸 N	orimin
Progestogen-only Contraceptives				

#### ⇒SA0500 Special Authority for Alternate Subsidy

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

1 Either:

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

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

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

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

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

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

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

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

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DE	300	20			
*	Tah	75	mca	_	11

✤ Tab 75 mcg – Up to 84 tab available on a PSO	84	<ul> <li>Cerazette</li> </ul>
LEVONORGESTREL		
* Tab 30 mcg – Up to 112 tab available on a PSO	112	<ul> <li>Microlut</li> </ul>
✤ Subdermal implant (2 × 75 mg rods) - Up to 6 impl available		
on a PSO106.92	2 OP	✓ Jadelle
MEDROXYPROGESTERONE ACETATE		
Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO10.56	1	Depo-Provera
		-

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
NORETHISTERONE Tab 350 mcg – Up to 84 tab available on a PSO	12.25	84	<b>~</b> 1	Norethinderone - CDC Noriday Noriday 28
Emergency Contraceptives				
LEVONORGESTREL * Tab 1.5 mg	1.75	1	<b>√</b>	Levonorgestrel BNM
<ul><li>a) Maximum of 2 tab per prescription</li><li>b) Up to 5 tab available on a PSO</li><li>c) Note: Direct Provision by a pharmacist permitted un</li></ul>	der the provisions in F	Part I	of Section /	Α.

### 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:

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

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

#### CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL

*	Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs – Up		
	to 168 tab available on a PSO5.08	168	✓ Ginet

### **Gynaecological Anti-infectives**

ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID		
Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate		
0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator 8.43	100 g OP	
(24.87)		Aci-Jel
CLOTRIMAZOLE		
* Vaginal crm 1% with applicators	35 g OP	<ul> <li>Clomazol</li> </ul>
* Vaginal crm 2% with applicators	20 g OP	<ul> <li>Clomazol</li> </ul>
MICONAZOLE NITRATE		
* Vaginal crm 2% with applicator	40 g OP	<ul> <li>Micreme</li> </ul>
NYSTATIN	-	
Vaginal crm 100,000 u per 5 g with applicator(s)	75 g OP	✓ Nilstat
5 7 1 5 11 (7	9	

### Myometrial and Vaginal Hormone Preparations

#### ERGOMETRINE MALEATE

Inj 500 mcg per ml, 1 ml ampoule – Up to 5 inj available on a		
PSO160.00	5	<ul> <li>DBL Ergometrine</li> </ul>
OESTRIOL		
* Crm 1 mg per g with applicator6.95	15 g OP	<ul> <li>Ovestin</li> </ul>
* Pessaries 500 mcg7.55	15	✓ Ovestin

### GENITO-URINARY SYSTEM

	Subsidy (Manufacturer's Pr \$	rice) Subs Per	Fully       Brand or         sidised       Generic         ✓       Manufacturer
OXYTOCIN – Up to 5 inj available on a PSO Inj 5 iu per ml, 1 ml ampoule Inj 10 iu per ml, 1 ml ampoule		5 5	<ul><li>✓ Oxytocin BNM</li><li>✓ Oxytocin BNM</li></ul>
OXYTOCIN WITH ERGOMETRINE MALEATE – Up to 5 inj avail Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampor		5	<ul> <li>Syntometrine</li> </ul>
Pregnancy Tests - hCG Urine			
BETA-HCG LOW SENSITIVITY URINE TEST KIT – Up to 15 tes	t available on a F	PSO	
Note: For use in abortion services only. Midstream		1 test OP	✓ CheckTop
PREGNANCY TESTS - HCG URINE			
<ul> <li>a) Up to 200 test available on a PSO</li> <li>b) Only on a PSO</li> </ul>			
Cassette	16.00	40 test OP	✓ <u>David One Step</u> <u>Cassette</u> <u>Pregnancy Test</u>
Urinary Agents			
For urinary tract Infections refer to INFECTIONS, Antibacterials, p	age 114		
5-Alpha Reductase Inhibitors			
FINASTERIDE – Special Authority see SA0928 below – Retail pr * Tab 5 mg		100	✓ <u>Ricit</u>
SA0928 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria: Both:	without further r	enewal unless	s notified for applications meeting
<ol> <li>Patient has symptomatic benign prostatic hyperplasia; and</li> <li>Either:</li> </ol>			
<ul><li>2.1 The patient is intolerant of non-selective alpha bloc</li><li>2.2 Symptoms are not adequately controlled with non-selective</li></ul>			ed; or
Alpha-1A Adrenoreceptor Blockers			
TAMSULOSIN HYDROCHLORIDE – Special Authority see SA10 Cap 400 mcg		il pharmacy 100	<ul> <li>Tamsulosin-Rex</li> </ul>
SA1032 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria: Both:	without further r	enewal unless	s notified for applications meeting
<ol> <li>Patient has symptomatic benign prostatic hyperplasia; and</li> <li>The patient is intolerant of non-selective alpha blockers or</li> </ol>		indicated.	
Other Urinary Agents			
OXYBUTYNIN			
* Tab 5 mg	5.42	100	<ul> <li>Alchemy Oxybutynin</li> </ul>

	Subsidy (Manufacturer's F \$	Price) Subs Per	Fully idised	Brand or Generic Manufacturer
POTASSIUM CITRATE				
Oral liq 3 mmol per ml – Special Authority see SA1083 belo Retail pharmacy		200 ml OP	✓ E	Biomed
SA1083 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals val Both:	d for 12 months t	for applications	meetir	ng the following criteria:
<ol> <li>The patient has recurrent calcium oxalate urolithiasis; and</li> <li>The patient has had more than two renal calculi in the two</li> </ol>		e application.		
Renewal from any relevant practitioner. Approvals valid for 2 yes benefitting from the treatment.	ars where the tre	eatment remain	s appro	opriate and the patient is
SODIUM CITRO-TARTRATE	2 50	00		
* Grans eff 4 g sachets SOLIFENACIN SUCCINATE	3.50	28	<b>√</b> <u>I</u>	
Tab 5 mg	1.95	30	✓ <u>s</u>	Solifenacin succinate Max
Tab 10 mg	3.15 3.53	30	-	<u>Health</u> Solifenacin Viatris Solifenacin <u>succinate Max</u>
(Solifenacin Viatris Tab 5 mg to be delisted 1 November 2025)				<u>Health</u>
Detection of Substances in Urine				
ORTHO-TOLIDINE  * Compound diagnostic sticks	7.50 (8.25)	50 test OP	ŀ	lemastix
TETRABROMOPHENOL <ul> <li>Blue diagnostic strips</li> </ul>		100 test OP	✓ #	Albustix
Obstetric Preparations				
Antinragaataranaa				

### Antiprogesterones

MIFEPRISTONE			
Tab 200 mg – Up to 15 tab available on a PSO		1	<ul> <li>Mifegyne</li> </ul>
	180.00	3	<ul> <li>Mifegyne</li> </ul>

	Subsidy (Manufacturer's Price) \$	l Subsid Per	Fully Brand or lised Generic ✓ Manufacturer
Calcium Homeostasis			
CALCITONIN * Inj 100 iu per ml, 1 ml ampoule	121.00	5	<ul> <li>Miacalcic</li> <li>Miacalcic S29 529</li> </ul>
CINACALCET – Special Authority see SA2170 below – Retail pha Tab 30 mg – Wastage claimable Tab 60 mg – Wastage claimable		28 28	<ul> <li><u>Cinacalet Devatis</u></li> <li><u>Cinacalet Devatis</u></li> </ul>

#### ⇒SA2170 Special Authority for Subsidy

Initial application — (parathyroid carcinoma or calciphylaxis) only from a nephrologist or endocrinologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has been diagnosed with a parathyroid carcinoma (see Note); and
  - 1.2 The patient has persistent hypercalcaemia (serum calcium greater than or equal to 3 mmol/L) despite previous first-line treatments including sodium thiosulfate (where appropriate) and bisphosphonates; and
  - 1.3 The patient is symptomatic; or
- 2 All of the following:
  - 2.1 The patient has been diagnosed with calciphylaxis (calcific uraemic 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 — (parathyroid carcinoma or calciphylaxis) 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.

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

All of the following:

- 1 Patient has primary hyperparathyroidism; and
- 2 Either:
  - 2.1 Patient has hypercalcaemia of more than 3 mmol/L with or without symptoms; or
  - 2.2 Patient has hypercalcaemia of more than 2.85 mmol/L with symptoms; and
- 3 Surgery is not feasible or has failed; and
- 4 Patient has other comorbidities, severe bone pain, or calciphylaxis.

**Initial application** — (secondary or tertiary hyperparathyroidism) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Patient has tertiary hyperparathyroidism and markedly elevated parathyroid hormone (PTH) with hypercalcaemia; or
  - 1.2 Patient has symptomatic secondary hyperparathyroidism and elevated PTH; and
- 2 Patient is on renal replacement therapy; and
- 3 Any of the following:

continued...

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

Subs (Manufactur \$	er's Price)	Fully Subsidised r	
ontinued			
<ul><li>3.1 Residual parathyroid tissue has not been localised despite rep</li><li>3.2 Parathyroid tissue is surgically inaccessible; or</li><li>3.3 Parathyroid surgery is not feasible.</li></ul>	eat unsucces	sful parathy	roid explorations; or
tenewal — (secondary or tertiary hyperparathyroidism) from any relevant pplications meeting the following criteria: ither:	int practitione	r. Approval	s valid for 12 months for
<ol> <li>The patient has had a kidney transplant, and following a treatment free parathyroid hormone (PTH) level to support ongoing cessation of treat</li> <li>The patient has not received a kidney transplant and trial of withdraw</li> </ol>	tment has not	t been reac	hed; or
OLEDRONIC ACID			
Inj 4 mg per 5 ml, vial15.6	5 1		Zoledronic acid Injection Mylan 529 Zoledronic acid Viatris
			<u>Humo</u>
Corticosteroids and Related Agents for Systemic Use			
ETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACE	TATE		
Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml			Oslastana
(36.9	6)		Celestone Chronodose
EXAMETHASONE			
♦ Tab 0.5 mg – Up to 60 tab available on a PSO1.8			Dexmethsone
Tab 4 mg – Up to 30 tab available on a PSO			Dexmethsone Biomed
Oral liq 1 mg per ml53.8 EXAMETHASONE PHOSPHATE	6 25 ml	OP V	Biomea
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 PSO7.8	6 10	1	Hameln
Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO 13.1	0 10	1	Hameln
LUDROCORTISONE ACETATE			
€ Tab 100 mcg8.0	5 100	) 🗸	Florinef
YDROCORTISONE	0 100		Deurlee
€ Tab 5 mg8.1 € Tab 20 mg			Douglas Douglas
Inj 100 mg vial			Solu-Cortef
a) Not on a BSO b) Up to 5 inj available on a PSO	<b>.</b> 1	-	
ETHYLPREDNISOLONE			
K Tab 4 mg	0 100	) 🗸	Medrol

	Subsidy		Fully	Brand or
	(Manufacturer's Pric	e) Subsi		Generic
	\$	Per	✓	Manufacturer
METHYLPREDNISOLONE (AS SODIUM SUCCINATE)			_	
Inj 40 mg vial		1	✓	Solu-Medrol-Act-
				O-Vial
Inj 125 mg vial	34 10	1	1	Solu-Medrol-Act-
		•	-	O-Vial
				0-viai
	40.04			
Inj 500 mg vial		1	v	Solu-Medrol-Act-
				O-Vial
			_	
Inj 1 g vial		1	1	Solu-Medrol
METHYLPREDNISOLONE ACETATE				
	47.00	F	./	Dono Madral
Inj 40 mg per ml, 1 ml vial		5	v	Depo-Medrol
PREDNISOLONE				
* Oral liq 5 mg per ml – Up to 30 ml available on a PSO	6.00	30 ml OP	1	Redipred
Restricted to children under 12 years of age.				
PREDNISONE				
* Tab 1 mg		500	✓	Prednisone Clinect
* Tab 2.5 mg	21.04	500	1	Prednisone Clinect
* Tab 5 mg – Up to 30 tab available on a PSO		500	-	Prednisone Clinect
				Prednisone Clinect
* Tab 20 mg – Up to 30 tab available on a PSO		500	v	Predhisone Clinect
TETRACOSACTRIN				
* Inj 250 mcg per ml, 1 ml ampoule	86.25	1	1	Synacthen
		•		UK Synacthen
Y Init management temporale	600.00	4		
* Inj 1 mg per ml, 1 ml ampoule		1		Synacthen Depot
			~	Synacthene
				Retard S29
TRIAMCINOLONE ACETONIDE				
	01.40	-		Kanagart A 10
Inj 10 mg per ml, 1 ml ampoule		5		Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule		5	~	Kenacort-A 40
Sex Hormones Non Contraceptive				
·				
Androgen Agonists and Antagonists				
, indiegen , igeniete und , indigeniete				
CYPROTERONE ACETATE				
Tab 50 mg	17.05	50	1	Siterone
Tab 100 mg		50	1	Siterone
Tab 100 mg		50	•	Siterone
TESTOSTERONE				
Gel (transdermal) 16.2 mg per g, 88 g		60 OP	1	Testogel
TESTOSTERONE CIPIONATE				
Inj 100 mg per ml, 10 ml vial		1	~	Depo-Testosterone
TESTOSTERONE ESTERS				
Inj 250 mg per ml, 1 ml	12 08	1	1	Sustanon Ampoules
			•	oustation Anipoules
TESTOSTERONE UNDECANOATE				
Cap 40 mg – Subsidy by endorsement		100	1	Steril-Gene S29
Subsidy by endorsement – subsidised for patients who				
1 November 2021 and the prescription is endorsed acc				
where there exists a record of prior dispensing of testo		e cap 40 mg i		
Inj 250 mg per ml, 4 ml vial		1	✓	Reandron 1000

▲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	Fully	Brand or
	acturer's Price) Su	bsidised	Generic
· · · · · · · · · · · · · · · · · · ·	\$ Per	1	Manufacturer

	Subsidy		Fully	Brand or
	(Manufacturer's Pric \$	ce) Sub Per	sidised ✓	Generic Manufacturer
Hormone Replacement Therapy - Systemic				
Oestrogens				
ESTRADIOL				
F Tab 1 mg		28 OP	_	
	(11.10)		E	strofem
F Tab 2 mg		28 OP	-	-tural and
Col (transdormal) 0.06% (ZEO mag/actuation)	(11.10)	90 a OD	-	strofem
<ul> <li>Gel (transdermal) 0.06% (750 mcg/actuation)</li> <li>Patch 25 mcg per day</li> </ul>		80 g OP 8		<u>strogel</u> stradiol TDP Mylan
	13.50	0		straderm MX \$29
	16.23			stradot
	21.35		_	yllana
a) No more than 2 patch per week	21.00			y nana
b) Only on a prescription				
Patch 50 mcg per day	9.26	8	✓ E	stradiol TDP Mylan
······································	10.75	-		stradiol Viatris
	14.50			straderm MX S29
	11.00			stradiol Sandoz
	15.79		✓ E	stradot
	21.55		✓ L	yllana
a) No more than 2 patch per week				
b) Only on a prescription				
Patch 75 mcg per day		8	✓ E	stradiol TDP Mylan
	11.88			stradiol Viatris
	14.50		🖌 E	stradiol Sandoz
	16.53		🖌 E	stradot
	22.37		✓ L	yllana
<ul> <li>a) No more than 2 patch per week</li> </ul>				
b) Only on a prescription				
Patch 100 mcg per day		8		stradiol TDP Mylan
	12.95			stradiol Viatris
	14.50			stradiol Sandoz
	15.50			straderm MX S29
	16.18		-	stradot
a) No more than 0 motols non-models	22.77		v L	yllana
<ul><li>a) No more than 2 patch per week</li><li>b) Only on a prescription</li></ul>				
	combor 2025)			
Estraderm MX <sup>\$29</sup> Patch 25 mcg per day to be delisted 1 De yllana Patch 25 mcg per day to be delisted 1 December 2025				
stradiol Viatris Patch 50 mcg per day to be delisted 1 December 2025				
Straderm MX <sup>s29</sup> Patch 50 mcg per day to be delisted 1 Determ				
stradient Mix and a rach so meg per day to be delisted if Delistradiol Sandoz Patch 50 meg per day to be delisted 1 Decem	nhar 2025)			
yllana Patch 50 mcg per day to be delisted 1 December 2025				
Estradiol Viatris Patch 75 mcg per day to be delisted 1 December 2020				
Estradiol Sandoz Patch 75 mcg per day to be delisted 1 Decem				
yllana Patch 75 mcg per day to be delisted 1 December 2025				
Estradiol Viatris Patch 100 mcg per day to be delisted 1 Decen				
Estradiol Sandoz Patch 100 mcg per day to be delisted 1 Dece	,			
Estraderm MX 🕸 Patch 100 mcg per day to be delisted 1 D	,			
3,	5)			

▲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		bsidised	Generic
	\$	Per	1	Manufacturer
OESTRADIOL VALERATE				
* Tab 1 mg	12.36	84		Progynova
* Tab 2 mg	12.36	84	~	Progynova
OESTROGENS				
* Conjugated, equine tab 300 mcg	3.01	28		
	(19.25)			Premarin
* Conjugated, equine tab 625 mcg	4.12	28		
	(19.25)			Premarin
Progestogens				
MEDROXYPROGESTERONE ACETATE				
* Tab 2.5 mg	6.56	30	1	Provera
	8.75	56	~	Provera
* Tab 5 mg	9.80	56	✓	Provera
	20.13	100	~	Provera
* Tab 10 mg		30	~	Provera
Progestogen and Oestrogen Combined Prepar	ations			
OESTRADIOL WITH NORETHISTERONE				
* Tab 1 mg with 0.5 mg norethisterone acetate		28 OP		
· · · · · · · · · · · · · · · · · · ·	(18.10)			Kliovance
* Tab 2 mg with 1 mg norethisterone acetate		28 OP		
	(18.10)			Kliogest
* Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg				
oestradiol tab (12) and 1 mg oestradiol tab (6)	5.40	28 OP		
	(18.10)			Trisequens
Other Oestrogen Preparations				
OESTRIOL				<b>•</b>
* Tab 2 mg	7.70	30	~	Ovestin
Other Progestogen Preparations				
LEVONORGESTREL				
* Intra-uterine device 52 mg		1	✓	Mirena
* Intra-uterine device 13.5 mg	215.60	1	✓	Jaydess
MEDROXYPROGESTERONE ACETATE				
Tab 100 mg		100	1	Provera HD
NORETHISTERONE				
<ul> <li>* Tab 5 mg – Up to 30 tab available on a PSO</li> </ul>	5 49	30	1	Primolut N
PROGESTERONE		00	-	
* Cap 100 mg	1/ 85	30	1	Utrogestan
		50	•	Unoyesian
Thyroid and Antithyroid Agents				
CARBIMAZOLE				
* Tab 5 mg	7.56	100	1	Neo-Mercazole
Ť				

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	)	Subsidised	Generic
	\$	Per	1	Manufacturer
LEVOTHYROXINE				
* Tab 25 mcg	5.55	90	1	Synthroid
* Tab 50 mcg	1.71	28	✓	Mercury Pharma
	5.79	90	✓	Synthroid
	64.28	1,000	) 🗸	Eltroxin
* Tablet 50 mcg		200	1	Eltroxin
* Tab 100 mcg	1.78	28	1	Mercury Pharma
•	6.01	90	1	Synthroid
	66.78	1,000	) 🖌	Eltroxin
* Tablet 100 mcg		200	1	Eltroxin
PROPYLTHIOURACIL - Special Authority see SA1199 below - I	Retail pharmacy			
Tab 50 mg		100	1	PTU S29

#### 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**

SC	MATROPIN (OMNITROPE) - Special Authority see SA2032 below	v – Retail pharn	nacy	
*	Inj 5 mg cartridge	80.21	1	<ul> <li>Omnitrope</li> </ul>
*	Inj 10 mg cartridge	80.21	1	<ul> <li>Omnitrope</li> </ul>
*	Inj 15 mg cartridge	139.50	1	<ul> <li>Omnitrope</li> </ul>

#### ⇒SA2032 Special Authority for Subsidy

Initial application — (growth hormone deficiency in children) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months for applications meeting the following criteria: Either:

- 1 Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of life, or from samples during established hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device); or
- 2 All of the following:
  - 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</p>
  - 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:

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

#### continued...

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: 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:

90

Subsidy		Fully	Brand or	
(Manufacturer's P		idised	Generic	
\$	Per	~	Manufacturer	

continued...

- 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/1.73m<sup>2</sup> as measured by the Schwartz method (Height(cm)/plasma creatinine (umol/l)) × 40 = corrected GFR (ml/min/1.73m<sup>2</sup>) 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/ m<sup>2</sup>/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 eximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon; and
- 5 Either:
  - 5.1 Both:
    - 5.1.1 The patient is aged two years or older; and
    - 5.1.2 There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months; or
  - 5.2 The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation.

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

	Subsidy	Fu	lly	Brand or
(Mar	nufacturer's Price)	Subsidise	ed	Generic
	\$	Per	/	Manufacturer

#### continued...

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
  - 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

continued...

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

continued...

3 All of the following:

- 3.1 The patient has had a Special Authority approval for somatropin for childhood deficiency in children and no longer meets the renewal criteria under this indication; and
- 3.2 The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses; and
- 3.3 The patient has severe growth hormone deficiency (see notes); and
- 3.4 The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex; and
- 3.5 The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®).

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

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

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

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

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

### **GnRH Analogues**

GOSERELIN Implant 3.6 mg, syringe	66.48	1	✓ Zoladex
Implant 10.8 mg, syringe		1	✓ Zoladex
LEUPRORELIN			
Additional subsidy by endorsement where the patient is a goserelin and the prescription is endorsed accordingly.	child or adolescent a	ind is unable	e to tolerate administration of
Inj 3.75 mg prefilled dual chamber syringe – Higher subs	idy of		
\$221.60 per 1 inj with Endorsement	66.48	1	
	(221.60)		Lucrin Depot 1-month
Inj 11.25 mg prefilled dual chamber syringe – Higher sub	sidy		
of \$591.68 per 1 inj with Endorsement		1	
	(591.68)		Lucrin Depot 3-month
Vasopressin Agonists			
DESMOPRESSIN			
Wafer 120 mcg	47.00	30	<ul> <li>Minirin Melt</li> </ul>
DESMOPRESSIN ACETATE			
Tab 100 mcg		30	🗸 Minirin
Tab 200 mcg		30	🗸 Minirin
Inj 4 mcg per ml, 1 ml		10	🗸 Minirin

60 OP

	Subsidy (Manufacturer's Price) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer
Other Endocrine Agents				
CABERGOLINE				
Tab 0.5 mg – Maximum of 2 tab per prescription; can be				
waived by Special Authority see SA2070 below		2	-	Oostinex
	17.94	8	✓ [	Oostinex
<ul> <li>SA2070 Special Authority for Waiver of Rule</li> <li>Initial application from any relevant practitioner. Approvals va the following criteria:</li> <li>Any of the following:         <ol> <li>Hyperprolactinemia; or</li> <li>Acromegaly*; or</li> <li>Inhibition of lactation.</li> </ol> </li> <li>Renewal — (for patients who have previously been funded)</li> </ul>				
practitioner. Approvals valid without further renewal unless noti which has expired and the treatment remains appropriate and the Note: Indication marked with * is an unapproved indication.	fied where the patient	has prev	iously he	
CLOMIFENE CITRATE Tab 50 mg	29.84	10	✓ N	Iylan Clomiphen <sup>S29</sup>
METYRAPONE				
Cap 250 mg	558.00	50	✓ N	letopirone

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	Sub	sidised	Generic
	\$	Per	1	Manufacturer
Anthelmintics				
ALBENDAZOLE - Special Authority see SA1318 below - Reta	il pharmacy			
Tab 400 mg		60	✓ E	skazole S29
SA1318 Special Authority for Subsidy				
<b>Initial application</b> only from an infectious disease specialist or patient has hydatids.	clinical microbiologist.	Approval	s valid f	or 6 months where the
Renewal only from an infectious disease specialist or clinical m	icrobiologist. Approva	ls valid fo	r 6 mon	ths where the treatment
remains appropriate and the patient is benefitting from the treat	ment.			
MEBENDAZOLE – Only on a prescription				
Tab 100 mg		6	<ul> <li>V</li> </ul>	/ermox
Oral liq 100 mg per 5 ml		15 ml		
	(7.83)		V	ermox
PRAZIQUANTEL				
Tab 600 mg	68.00	8	✓ E	Biltricide
Antibacterials				
	07			
<ul><li>a) For topical antibacterials, refer to DERMATOLOGICALS, pa</li><li>b) For anti-infective eye preparations, refer to SENSORY ORG</li></ul>				
Cephalosporins and Cephamycins				
CEFACLOR MONOHYDRATE				
Cap 250 mg		100	✓ F	anbaxy-Cefaclor
Grans for oral liq 125 mg per 5 ml - Wastage claimable		100 ml		anbaxy-Cefaclor
CEFALEXIN				-
Cap 250 mg		20	✓ (	Cephalexin ABM
Cap 500 mg	5.85	20		Cephalexin ABM
Grans for oral liq 25 mg per ml – Wastage claimable	7.88	100 ml	🗸 F	lynn
Grans for oral liq 50 mg per ml – Wastage claimable		100 ml		lynn
	11.75		✓ (	Cefalexin Sandoz
CEFAZOLIN – Subsidy by endorsement				
Only if prescribed for dialysis or cellulitis in accordance with	a Health NZ Hospital	approved	protoco	ol and the prescription is
endorsed accordingly.	0.00	-		
Inj 500 mg vial Inj 1 g vial		5 5		Cefazolin-AFT Cefazolin-AFT
Inj 2 g vial		5 5	_	Cefazolin-AFT
, .		5	• •	
CEFTRIAXONE – Subsidy by endorsement a) Up to 10 inj available on a PSO				
<ul> <li>b) Subsidised only if prescribed for a dialysis or cystic fibro pelvic inflammatory disease, or the treatment of suspect endorsed accordingly.</li> </ul>				
Inj 500 mg vial	0.79	1	✓ (	Ceftriaxone-AFT
Inj 1 g vial		5		Ceftriaxone-AFT
CEFUROXIME AXETIL – Subsidy by endorsement				
Only if prescribed for prophylaxis of endocarditis and the pr	escription is endorsed	according	gly.	
Tab 250 mg	CBS	20	A      A  A     A	scend-
				Cefuroxime S29

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

	Subsidy (Manufacturer's Price) \$	Subs Per	Fully idised	Brand or Generic Manufacturer
Macrolides				
AZITHROMYCIN – Maximum of 5 days treatment per prescriptio A maximum of 24 months of azithromycin treatment for non-or Authority. Tab 250 mg	cystic fibrosis bronch		l be su	
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		15 ml	✓ Z	lithromax
SA1683 Special Authority for Waiver of Rule Initial application — (bronchiolitis obliterans syndrome, cyst	ic fibrosis and atyp	ical Mycol	bacteri	ium infections) only fro

a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria: Any of the following:

- 1 Patient has received a lung transplant, stem cell transplant, or bone marrow transplant and requires treatment for bronchiolitis obliterans syndrome\*; or
- 2 Patient has received a lung transplant and requires prophylaxis for bronchiolitis obliterans syndrome\*; or
- 3 Patient has cystic fibrosis and has chronic infection with Pseudomonas aeruginosa or Pseudomonas-related gram negative organisms\*; or
- 4 Patient has an atypical Mycobacterium infection.
- Note: Indications marked with \* are unapproved indications.

**Initial application — (non-cystic fibrosis bronchiectasis\*)** only from a respiratory specialist or paediatrician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 For prophylaxis of exacerbations of non-cystic fibrosis bronchiectasis\*; and
- 2 Patient is aged 18 and under; and
- 3 Either:
  - 3.1 Patient has had 3 or more exacerbations of their bronchiectasis, within a 12 month period; or
  - 3.2 Patient has had 3 acute admissions to hospital for treatment of infective respiratory exacerbations within a 12 month period.

Note: Indications marked with \* are unapproved indications.

Renewal — (non-cystic fibrosis bronchiectasis\*) only from a respiratory specialist or paediatrician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has completed 12 months of azithromycin treatment for non-cystic fibrosis bronchiectasis; and
- 2 Following initial 12 months of treatment, the patient has not received any further azithromycin treatment for non-cystic fibrosis bronchiectasis for a further 12 months, unless considered clinically inappropriate to stop treatment; and
- 3 The patient will not receive more than a total of 24 months' azithromycin cumulative treatment (see note).

The patient must not have had more than 1 prior approval.

Note: No further renewals will be subsidised. A maximum of 24 months of azithromycin treatment for non-cystic fibrosis bronchiectasis will be subsidised. Indications marked with \* are unapproved indications

CLARITHROMYCIN - Maximum of 500 mg per prescription; can be waived by Special Authority see SA1857 below

Tab 250 mg7.31	12	<ul> <li>Klaricid S29</li> </ul>
8.53	14	<ul> <li>Klacid</li> </ul>
Grans for oral liq 250 mg per 5 ml – Wastage claimable192.00	50 ml	<ul> <li>Klacid</li> </ul>

#### ⇒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:

continued...

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

continued...

Either:

1 Atypical mycobacterial infection; or

2 Mycobacterium tuberculosis infection where there is drug-resistance or intolerance to standard pharmaceutical agents. **Initial application — (Helicobacter pylori eradication)** from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

Both:

1 For the eradication of helicobacter pylori in a patient unable to swallow tablets; and

2 For use only in combination with omeprazole and amoxicillin as part of a triple therapy regimen.

Initial application — (Prophylaxis of infective endocarditis) from any relevant practitioner. Approvals valid for 3 months where prophylaxis of infective endocarditis associated with surgical or dental procedures if amoxicillin is contra-indicated. Renewal — (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment. ENTHROMYCIN (AS LACTORIONATE)

Inj 1 g vial		1	<ul> <li>Erythrocin IV</li> </ul>
ERYTHROMYCIN ETHYL SUCCINATE			-
Tab 400 mg	35.82	100	<ul> <li>E-Mycin</li> </ul>
<ul> <li>a) Up to 20 tab available on a PSO</li> <li>b) Up to 2 x the maximum PSO quantity for RFPP</li> <li>Grans for oral lig 200 mg per 5 ml</li> </ul>	6 53	100 ml	✓ E-Mycin
<ul><li>a) Up to 300 ml available on a PSO</li><li>b) Up to 2 x the maximum PSO quantity for RFPP</li></ul>		100 111	
<ul> <li>c) Wastage claimable</li> <li>Grans for oral liq 400 mg per 5 ml</li> <li>a) Up to 200 ml available on a PSO</li> <li>b) Wastage claimable</li> </ul>	9.41	100 ml	E-Mycin
ROXITHROMYCIN			
Tab 150 mg	13.19	50	✓ <u>Arrow-</u> <u>Roxithromycin</u>
Tab 300 mg	25.00	50	✓ <u>Arrow-</u> <u>Roxithromycin</u>

	Subsidy (Manufacturer's Price \$	) Su Per	Fully ubsidised	Brand or Generic Manufacturer
Penicillins				
AMOXICILLIN			<i>.</i>	
Cap 250 mg a) Up to 30 cap available on a PSO	27.50	500	✓ M	iro-Amoxicillin
b) Up to 10 x the maximum PSO guantity for RFPP				
Cap 500 mg	41.00	500	🗸 М	iro-Amoxicillin
a) Up to 30 cap available on a PSO				
<li>b) Up to 10 x the maximum PSO quantity for RFPP Grans for oral liq 125 mg per 5 ml</li>	0.00	100 ml	<b>1</b> AI	phamox 125
a) Up to 200 ml available on a PSO		100 111	• <u>A</u>	
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	2.81	100 ml	✓ <u>A</u>	phamox 250
a) Up to 300 ml available on a PSO				
<ul> <li>b) Up to 10 x the maximum PSO quantity for RFPP</li> <li>c) Wastage claimable</li> </ul>				
Inj 250 mg vial	15.97	10	🖌 lb	iamox
Inj 500 mg vial		10	✔ lb	iamox
Inj 1 g vial – Up to 5 inj available on a PSO	21.64	10	🖌 Ib	iamox
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg – Up to 30 tab				<b>B </b> //
available on a PSO		10	✓ <u>Ci</u>	uram Duo 500/125
Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25 i per ml		100 ml	🗸 Δι	ugmentin
a) Up to 200 ml available on a PSO		100 111	- <u>A</u>	<u>ugnonin</u>
b) Wastage claimable				
Grans for oral liq amoxicillin 50 mg with clavulanic acid 12.5				
per ml – Up to 200 ml available on a PSO	5.61 1	00 ml OP		<u>moxiclav Devatis</u> Forto
BENZATHINE BENZYLPENICILLIN				Forte
Inj 900 mg (1.2 million units) in 2.3 ml syringe – Up to 5 inj				
available on a PSO		10	🗸 Bi	cillin LA
BENZYLPENICILLIN SODIUM [PENICILLIN G]				
Inj 600 mg (1 million units) vial - Up to 5 inj available on a P	SO 16.50	10	🗸 <u>Sa</u>	andoz

	Subsidy (Manufacturer's Price)	Per	Fully Subsidised	Generic
	\$	Per	•	Manufacturer
FLUCLOXACILLIN	15 70	050		Flucloxacillin-AFT
Cap 250 mg – Up to 30 cap available on a PSO	15.79 22.58	250		Staphlex
Staphlex to be Principal Supply on 1 August 2025	22.50		•	Staphiex
Cap 500 mg – Up to 30 cap available on a PSO	52 99	500	1	Flucloxacillin-AFT
	72.71	000		Staphlex
Staphlex to be Principal Supply on 1 August 2025	,, ,		-	otaphilox
Grans for oral liq 25 mg per ml		100 m	l 🗸	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral lig 50 mg per ml		100 m	l 🗸	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Inj 250 mg vial		10	1	Flucloxin
Inj 500 mg vial		10	1	Flucloxin
Inj 1 g vial – Up to 5 inj available on a PSO		5	✓	Flucil
(Flucloxacillin-AFT Cap 250 mg to be delisted 1 August 2025)				
(Flucloxacillin-AFT Cap 500 mg to be delisted 1 August 2025)				
PHENOXYMETHYLPENICILLIN (PENICILLIN V)				
Cap 250 mg – Up to 30 cap available on a PSO	7.68	50	1	Cilicaine VK
Cap 500 mg		50		Cilicaine VK
a) Up to 20 cap available on a PSO		00		
b) Up to 2 x the maximum PSO quantity for RFPP				
Grans for oral liq 125 mg per 5 ml		100 m	· ·	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	4.24	100 m	l 🗸	AFT
a) Up to 300 ml available on a PSO				
b) Up to 2 x the maximum PSO guantity for RFPP				
c) Wastage claimable				
Tetracyclines				
renacycinies				
DOXYCYCLINE				
* Tab 100 mg – Up to 30 tab available on a PSO	64.43	500	1	Doxine
MINOCYCLINE HYDROCHLORIDE				
* Tab 50 mg – Additional subsidy by Special Authority see				
SA1355 below – Retail pharmacy	5.79	60		
	(12.05)			Mino-tabs
* Cap 100 mg		100		
	(52.04)			Minomycin
⇒SA1355 Special Authority for Manufacturers Price				
Initial application from any relevant practitioner. Approvals val	id without further rene	ewal ur	nless notif	ied where the patient has
rosacea.				
TETRACYCLINE - Special Authority see SA1332 on the next p	•			
Tab 250 mg	68.44	28	✓	Accord S29

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
SA1332 Special Authority for Subsidy itial application from any relevant practitioner. Approvals v oth:	valid for 3 months for ap	plicati	ons meetin	g the following criteria:
<ol> <li>For the eradication of helicobacter pylori following unsu</li> <li>For use only in combination with bismuth as part of a q</li> </ol>			opriate first-	line therapy; and
Other Antibiotics				
or topical antibiotics, refer to DERMATOLOGICALS, page 67	,			
IPROFLOXACIN				
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	1 95	28		pca-Ciprofloxacin
Tab 500 mg – Up to 5 tab available on a PSO		28		pca-Ciprofloxacin
Tab 750 mg		28		pca-Ciprofloxacin
LINDAMYCIN				<u> </u>
Cap hydrochloride 150 mg	4 94	24	1	Dalacin C
Inj 150 mg per ml, 4 ml ampoule		10		Hameln
COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist		ent		
Only if prescribed for dialysis or cystic fibrosis patient and			accordingly	
Inj 2 million iu, 10 ml vial		10	• •	Colomycin S29
ENTAMICIN SULPHATE				···· <b>/</b> ·
Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement		5	1	Cidomycin
,				P/Free S29
Only if prescribed for a dialysis or cystic fibrosis patie	nt or complicated urinar	y tract	t infection a	
endorsed accordingly.				
Inj 10 mg per ml, 1 ml ampoule - Subsidy by endorsemen		5		DBL Gentamicin
Only if prescribed for a dialysis or cystic fibrosis patie	nt or complicated urinar	y trac	t infection a	nd the prescription is
endorsed accordingly.		_		
Inj 10 mg per ml, 2 ml ampoule – Subsidy by endorsemen		5		Wockhardt S29
Only if prescribed for a dialysis or cystic fibrosis patie endorsed accordingly.	nt or complicated urinar	y trac	infection a	nd the prescription is
Inj 40 mg per ml, 2 ml ampoule – Subsidy by endorseme	nt 18.38	10	1	Gentamicin
	10.00	10	•	Amdipharm \$29
			1	Pfizer
	91.90	50		Gentamicin
	01.00	50	•	Noridem S29
Only if prescribed for a dialysis or cystic fibrosis patie endorsed accordingly.	nt or complicated urinar	y trac	t infection a	
Wockhardt see Inj 10 mg per ml, 2 ml ampoule to be deliste	d 1 October 2025)			
IOXIFLOXACIN - Special Authority see SA1740 on the next	,	у		
No patient co-payment payable Tab 400 mg	40.00	~		A
	42 (10	5	v ,	Avelox

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

#### ⇒SA1740 Special Authority for Subsidy

**Initial application — (Tuberculosis)** only from a respiratory specialist or infectious disease specialist. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Both:
  - 1.1 Active tuberculosis\*; and
  - 1.2 Any of the following:
    - 1.2.1 Documented resistance to one or more first-line medications; or
    - 1.2.2 Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents; or
    - 1.2.3 Impaired visual acuity (considered to preclude ethambutol use); or
    - 1.2.4 Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or
    - 1.2.5 Significant documented intolerance and/or side effects following a reasonable trial of first-line medications; or
- 2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated.\*; or

3 Patient is under five years of age and has had close contact with a confirmed multi-drug resistant tuberculosis case.

Note: Indications marked with \* are unapproved indications.

Renewal only from a respiratory specialist or infectious disease specialist. Approvals valid for 1 year where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (Mycoplasma genitalium) only from a sexual health specialist or Practitioner on the recommendation of a sexual health specialist. Approvals valid for 1 month for applications meeting the following criteria: All of the following:

- 1 Has nucleic acid amplification test (NAAT) confirmed Mycoplasma genitalium\* and is symptomatic; and
- 2 Either:
  - 2.1 Has tried and failed to clear infection using azithromycin; or
  - 2.2 Has laboratory confirmed azithromycin resistance; and
- 3 Treatment is only for 7 days.

**Initial application** — (Penetrating eye injury) only from an ophthalmologist. Approvals valid for 1 month where the patient requires prophylaxis following a penetrating eye injury and treatment is for 5 days only. Note: Indications marked with \* are unapproved indications.

PAROMOMYCIN – Special Authority see SA1689 below – Retail pharmacy

Cap 250 mg		16	<ul> <li>Humatin S29</li> </ul>
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#### ⇒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:

Either:

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

PYRIMETHAMINE	- Special Aut	ority see SA1328	on the next page	<mark>ge</mark> – Retail pharmacy
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30

✓ Daraprim S29

(Daraprim S29) Tab 25 mg to be delisted 1 October 2025)

	Subsidy (Manufacturer's Price) \$	) S Per	Fully ubsidised ✓	Brand or Generic Manufacturer
<ul> <li>SA1328 Special Authority for Subsidy</li> <li>Initial application from any relevant practitioner. Approvals valit the following criteria:</li> <li>Any of the following:         <ol> <li>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</li> </ol> </li> </ul>	r a period of 3 month		ess notified	d for applications meeting
SODIUM FUSIDATE [FUSIDIC ACID]	405 70	00		
Tab 250 mg SULFADIAZINE SODIUM – Special Authority see SA1331 below		36	¥ F	ucidin
Tab 500 mg		100	✓ s	ulfadiazin-Heyl S29
Ū	543.20	56	🗸 W	/ockhardt S29
(Wockhardt S29) Tab 500 mg to be delisted 1 October 2025)	010.20	00		
<ul> <li>the following criteria:</li> <li>Any of the following:</li> <li>1 For the treatment of toxoplasmosis in patients with HIV for</li> <li>2 For pregnant patients for the term of the pregnancy; or</li> <li>3 For infants with congenital toxoplasmosis until 12 months</li> </ul>		ns; or		
TOBRAMYCIN Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement Only if prescribed for dialysis or cystic fibrosis patient ar		5 endorse		<b>obramycin (Viatris)</b> gly.
Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsementa) Wastage claimable		56 dose	✓ <u>T</u>	obramycin BNM
b) Only if prescribed for a cystic fibrosis patient and the	prescription is endo	rsed acc	ordingly.	
TRIMETHOPRIM * Tab 300 mg – Up to 30 tab available on a PSO TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMO> * Tab trimethoprim 80 mg and sulphamethoxazole 400 mg –	(AZOLE]	50	✓ <u>⊺</u>	MP
to 30 tab available on a PSO		500	✓ <u>⊺</u>	risul
<ul> <li>Oral liq 8 mg sulphamethoxazole 40 mg per ml – Up to 200 available on a PSO</li></ul>		100 ml	✔ D	eprim
VANCOMYCIN – Subsidy by endorsement				
Only if prescribed for a dialysis or cystic fibrosis patient or fo difficile following metronidazole failure and the prescription is	r prophylaxis of endo s endorsed according	ocarditis alv.	or for treat	ment of Clostridium
Inj 500 mg vial		1	✓ <u>M</u>	lylan

	0.1.11			<u> </u>
	Subsidy		Fully	Brand or
	(Manufacturer's F \$	Price) Sub: Per	sidised	Generic Manufacturer
	φ	Fei	•	Manulaciulei
Antifungals				
<ul> <li>a) For topical antifungals refer to DERMATOLOGICALS, page 6</li> <li>b) For topical antifungals refer to GENITO URINARY, page 80</li> </ul>	8			
FLUCONAZOLE				
Cap 50 mg	4 10	28	🗸 M	lylan
Cap 150 mg		1		lylan
Cap 200 mg		28		lylan
Powder for oral suspension 10 mg per ml – Special Authority		20	• <u>n</u>	rynan
see SA1359 below – Retail pharmacy		35 ml	<b>.</b> n	iflucan
Wastage claimable		33 111	• 0	illucali
3				
■SA1359 Special Authority for Subsidy Initial application — (Systemic candidiasis) from any relevant	prostitionar Ar	provale valid f	or 6 wo	ake for applications
meeting the following criteria:	practitioner. Ap	piovais valiu i		ens for applications
Both:				
1 Patient requires prophylaxis for, or treatment of systemic of	candidiasis; and			
2 Patient is unable to swallow capsules.				
Initial application — (Immunocompromised) from any relevant	t practitioner. A	pprovals valid	for 6 mo	onths for applications
meeting the following criteria:				
All of the following:				
<ol> <li>Patient is immunocompromised; and</li> </ol>				
2 Patient is at moderate to high risk of invasive fungal infect	ion; and			
3 Patient is unable to swallow capsules.				
Renewal — (Systemic candidiasis) from any relevant practition	ner. Approvals v	alid for 6 week	s for ap	plications meeting the
following criteria:				
Both:				
1 Patient requires prophylaxis for, or treatment of systemic of	candidiasis; and			
2 Patient is unable to swallow capsules.				
Renewal — (Immunocompromised) from any relevant practitio	ner. Approvals	valid for 6 mon	ths for a	applications meeting the
following criteria:	·			<b>J</b>
All of the following:				
1 Patient remains immunocompromised; and				
<ol> <li>Patient remains at moderate to high risk of invasive fungal</li> </ol>	l infection: and			
3 Patient is unable to swallow capsules.				
ITRACONAZOLE				
Cap 100 mg		15	• It	raconazole
				Cresent S29
			🖌 lt	razole
	27.32	60	🗸 lt	racap S29
Oral liq 10 mg per ml – Special Authority see SA1322 below	-			
Retail pharmacy	141.80	150 ml OP	🖌 lt	raconazole
· ·				Kent S29
(Itracap 329) Cap 100 mg to be delisted 1 December 2025)				

#### ► 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.

▲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

ubsidy cturer's Price) \$ F	Fully Subsidised Per ✓	Generic
BS 3	0 🗸	Burel S29
1(	· ·	Strides Shasun S29 Taro S29 Teva- Ketoconazole S29
.16 5	0	
7.09) 2.81 5	0	Nilstat
5.47)		Nilstat
		Posaconazole Juno
	9.60 2	3.60 24 🗸

#### ⇒SA2383 Special Authority for Subsidy

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

Either:

- 1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation chemotherapy; or
- 2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppressive therapy\*.

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

Either:

- 1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation therapy; or
- 2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppression\* and requires on going posaconazole treatment.

Note: \* Graft versus host disease (GVHD) on significant immunosuppression is defined as acute GVHD, grade II to IV, or extensive chronic GVHD, or if they were being treated with intensive immunosuppressive therapy consisting of either high-dose corticosteroids (1 mg or greater per kilogram of body weight per day for patients with acute GVHD or 0.8 mg or greater per kilogram every other day for patients with chronic GVHD), antithymocyte globulin, or a combination of two or more immunosuppressive agents or types of treatment.

**Initial application — (Invasive fungal infection prophylaxis)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 The patient is at risk of invasive fungal infection; and

2 Either:

- 2.1 Posaconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist; or
- 2.2 Prescribing posaconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI).

Renewal — (Invasive fungal infection prophylaxis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Both:

Subsidy	F	ully	Brand or
(Manufacturer's Price)	Subsidis	sed	Generic
 \$	Per	~	Manufacturer

continued...

- 1 The patient is at risk of invasive fungal infection; and
- 2 Either:
  - 2.1 Posaconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist; or
  - 2.2 Prescribing posaconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI).

#### TERBINAFINE

* Tab 250 mg8.97	84	<ul> <li>Deolate</li> </ul>
VORICONAZOLE - Special Authority see SA2384 below - Retail pharmacy		
Tab 50 mg	56	<ul> <li>Vttack</li> </ul>
Vttack to be Principal Supply on 1 August 2025		
Tab 200 mg263.00	56	<ul> <li>Vttack</li> </ul>
Vttack to be Principal Supply on 1 August 2025		
Powder for oral suspension 40 mg per ml – Wastage		
claimable1,523.22	70 ml	<ul> <li>Vfend</li> </ul>

#### ► SA2384 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.

Initial application — (Invasive fungal infection prophylaxis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

- Both:
  - 1 The patient is at risk of invasive fungal infection; and
  - 2 Either:
    - 2.1 Voriconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist; or
    - 2.2 Prescribing voriconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal

Sub	sidy F	ully Brand o	or
(Manufactu	urer's Price) Subsidi	sed Generic	;
\$	\$Per	<ul> <li>Manufa</li> </ul>	cturer

continued...

infection (IFI).

Renewal — (Invasive fungal infection prophylaxis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 The patient is at risk of invasive fungal infection; and

2 Either:

- 2.1 Voriconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist; or
- 2.2 Prescribing voriconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI).

Antimalarials		
PRIMAQUINE – Special Authority see SA1684 below – Retail pharmacy		
Tab 15 mg400.00	100	<ul> <li>Sanofi</li> </ul>
		Primaquine S29
► 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		250	<ul> <li>Metronidamed</li> </ul>
Tab 400 mg – Up to 15 tab available on a PSO	4.29	21	<ul> <li>Metronidamed</li> </ul>
Oral liq benzoate 200 mg per 5 ml		100 ml	Flagyl-S
Suppos 500 mg		10	<ul> <li>Flagyl</li> </ul>
ORNIDAZOLE			
Tab 500 mg		10	<ul> <li>Arrow-Ornidazole</li> </ul>

### **Antituberculotics and Antileprotics**

Note: There is no co-payment charge for all pharmaceuticals listed in the Antituberculotics and Antileprotics group regardless of immigration status.

BEDAQUILINE - Special Authority see SA2244 on the next page - Retail pharmacy

No patient co-payment payable

Гаb 100mg .	 	 	3,084.51	24 OP	1	Sirtur	3

	Subsidy (Manufacturer's Price \$	e) Sub Per	Fully osidised	Brand or Generic Manufacturer
<ul> <li>SA2244 Special Authority for Subsidy</li> <li>Initial application — (multi-drug resistant tuberculosis) from applications meeting the following criteria:</li> <li>Both:</li> <li>1 The person has multi-drug resistant tuberculosis (MDR-T</li> </ul>		ioner. App	provals va	alid for 6 months for
<ol> <li>Ministry of Health's Tuberculosis Clinical Network has rev of the treatment regimen.</li> </ol>		case and	recomme	ends bedaquiline as part
CLOFAZIMINE – Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on the recommendation dermatologist.</li> </ul>				-
* Cap 50 mg		100	🗸 Li	amprene S29
CYCLOSERINE – Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on the recommendative respiratory physician.</li> <li>Cap 250 mg</li> </ul>		disease pł 60		clinical microbiologist or
DAPSONE – Retail pharmacy-Specialist		00		yololini 👄
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on the recommendation dermatologist</li> <li>Tab 25 mg</li> </ul>		disease ph		Ū
Tab 100 mg		100		apsone apsone
ETHAMBUTOL HYDROCHLORIDE – Retail pharmacy-Speciali		100		apsone
a) No patient co-payment payable	51			
<ul> <li>b) Prescriptions must be written by, or on the recommendative respiratory physician</li> </ul>	tion of, an infectious	disease pł	nysician,	clinical microbiologist or
Tab 100 mg	85.73	100	🖌 E	MB Fatol S29
Tab 400 mg	49.34	56	🗸 M	yambutol S29
ISONIAZID – Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on the recommendal microbiologist, dermatologist or public health physician</li> </ul>	tion of, an internal m	edicine phy	ysician, p	aediatrician, clinical
* Tab 100 mg	94.50 327.41	100		oniazid Teva S29 oumed Isoniazid
ISONIAZID WITH RIFAMPICIN – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation	tion of an internal m	odioino nh	voicion r	andiatriainn aliniaal
microbiologist, dermatologist or public health physician	lion of, an internal in	edicine pri	ysician, p	aeulatriciari, cirricai
<ul> <li>* Tab 100 mg with rifampicin 150 mg</li> <li>* Tab 150 mg with rifampicin 300 mg</li> </ul>		100 100		<u>ifinah</u> ifinah
LINEZOLID – Special Authority see SA2234 on the next page – No patient co-payment payable	Retail pharmacy			
Tab 600 mg		10		<u>yvox</u>
Oral liq 20 mg per ml	1,879.00	150 ml	✓ Z	yvox

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

	Subsidy (Manufacturer's P \$	rice) Sub Per	Fully Brand or osidised Generic Manufacture	ər
SA2234 Special Authority for Subsidy Initial application — (multi-drug resistant tube applications meeting the following criteria: Both:	erculosis) from any relevant pra	ctitioner. App	provals valid for 18 m	onths for
<ol> <li>The person has multi-drug resistant tuber</li> <li>Ministry of Health's Tuberculosis Clinical I the treatment regimen.</li> </ol>		ual case and	recommends linezoli	d as part of
PARA-AMINO SALICYLIC ACID – Retail pharma	acy-Specialist			
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on th respiratory physician</li> </ul>		us disease sp	pecialist, clinical micr	obiologist or
Grans for oral liq 4 g sachet		30	Paser S29	
PROTIONAMIDE – Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on th respiratory physician</li> </ul>				obiologist or
Tab 250 mg		100	Peteha S29	
PYRAZINAMIDE – Retail pharmacy-Specialist				
<ul><li>a) No patient co-payment payable</li><li>b) Prescriptions must be written by, or on th respiratory physician</li></ul>				-
* Tab 500 mg	64.95	100	<ul> <li>AFT-Pyrazina</li> </ul>	amide
RIFABUTIN – Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on th gastroenterologist</li> </ul>		us disease pł	nysician, respiratory (	ohysician or
* Cap 150 mg		30	<ul> <li>Mycobutin</li> </ul>	
RIFAMPICIN – Subsidy by endorsement				
<ul> <li>a) No patient co-payment payable</li> <li>b) For confirmed recurrent Staphylococcus a antimicrobial based on susceptibilities an Retail pharmacy - Specialist. Specialist r paediatrician, or public health physician.</li> <li>* Cap 150 mg</li> </ul>	d the prescription is endorsed ac nust be an internal medicine phy 	cordingly; car	n be waived by endor I microbiologist, derm <u>     Kifadin</u> <u>     Rifadin</u>	sement - natologist,
* Oral liq 100 mg per 5 ml		60 ml	<ul> <li>Rifadin Sand</li> <li><u>Rifadin</u></li> </ul>	fi
Antivirals				
For eye preparations refer to Eye Preparations, A	Anti-Infective Preparations, page	276		
Hepatitis B Treatment				
ENTECAVIR	10.04	00	. Entropy in (D	••••
* Tab 0.5 mg		30	<ul> <li>Entecavir (Relation)</li> </ul>	<u>=x</u> ]
LAMIVUDINE – Special Authority see SA1685 o Tab 100 mg Oral liq 5 mg per ml		28 240 ml OP	✓ <u>Zetlam</u> ✓ Zeffix	
108  fully subsidised Principal Supply	S29 Unapp Sole Subsid		supplied under Section	29

	Subsidy		Fully	Brand or
	Manufacturer's Price)	Subsid	dised	Generic
	\$	Per	1	Manufacturer
SA1685 Special Authority for Subsidy				
nitial application only from a relevant specialist or medical practi	ioner on the recomr	nendation of	of a rel	evant specialist.
Approvals valid for 1 year where used for the treatment or preventi				
Renewal from any relevant practitioner. Approvals valid for 2 year		e treatment	or pre	evention of hepatitis B.
TENOFOVIR DISOPROXIL				
Tenofovir disoproxil prescribed under endorsement for the trea	tment of HIV is inclu	ided in the	count	of up to 4 subsidised
antiretrovirals for the purposes of Special Authority SA2139., p			oount	
<ul> <li>* Tab 245 mg (300 mg as a maleate)</li> </ul>	•	30	🗸 T(	enofovir Disoproxil
				Viatris
* Tab 245 mg (300 mg as a fumarate)	13 80	30	🗸 R	icovir S29
Herpesvirus Treatments				
ACICLOVIR				
* Tab dispersible 200 mg		25	🗸 Lo	ovir
* Tab dispersible 400 mg		56	🗸 Lo	ovir
* Tab dispersible 800 mg		35	🗸 Li	ovir
/ALACICLOVIR				
Tab 500 mg	9 64	30	🗸 V	aclovir
Tab 1,000 mg		30		aclovir
-			-	
VALGANCICLOVIR – Special Authority see SA1993 below – Reta		<u></u>	. A 14	al namalal avdu
Tab 450 mg	140.89	60	• 1	alganciclovir Vietrie
				Viatris

#### ⇒SA1993 Special Authority for Subsidy

**Initial application** — (transplant cytomegalovirus prophylaxis) only from a relevant specialist. Approvals valid for 3 months where the patient has undergone a solid organ transplant and requires valganciclovir for CMV prophylaxis.

Renewal — (transplant cytomegalovirus prophylaxis) only from a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 Patient has undergone a solid organ transplant and received anti-thymocyte globulin and requires valganciclovir therapy for CMV prophylaxis; and
- 1.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following anti-thymocyte globulin; or

2 Both:

- 2.1 Patient has received pulse methylprednisolone for acute rejection and requires further valganciclovir therapy for CMV prophylaxis; and
- 2.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following pulse methylprednisolone.

**Initial application — (cytomegalovirus prophylaxis following anti-thymocyte globulin)** only from a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

- Both:
  - 1 Patient has undergone a solid organ transplant and received valganciclovir under Special Authority more than 2 years ago (27 months); and
  - 2 Patient has received anti-thymocyte globulin and requires valganciclovir for CMV prophylaxis.

Renewal — (cytomegalovirus prophylaxis following anti-thymocyte globulin) only from a relevant specialist. Approvals valid for 3 months where the patient has received a further course of anti-thymocyte globulin and requires valganciclovir for CMV prophylaxis.

**Initial application** — (Lung transplant cytomegalovirus prophylaxis) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Subsidy	Fi	ully Brand or
(Manufacturer's	Price) Subsidis	sed Generic
\$	Per	<ul> <li>Manufacturer</li> </ul>

#### continued...

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 d website https://pharmac.govt.nz/maviret	irect distribution supp	oly. Further c	letails can be found on Phan	mac's
Tab 100 mg with pibrentasvir 40 mg	24,750.00	84 OP	<ul> <li>Maviret</li> </ul>	
LEDIPASVIR WITH SOFOSBUVIR - [Xpharm] - Special Aut	hority see SA1605 be	elow		
No patient co-payment payable				
Tab 90 mg with sofosbuvir 400 mg	24,363.46	28	<ul> <li>Harvoni</li> </ul>	
➡SA1605 Special Authority for Subsidy				
Special Authority approved by the Hepatitis C Treatment Pane	el (HepCTP)			
Notes: By application to the Hepatitis C Treatment Panel (He	pCTP).			
Applications will be considered by HepCTP and approved sub	ject to confirmation o	f eligibility.		
Application details may be obtained from Pharmac's website	http://www.pharmac.g	ovt.nz/mavire	et or:	
The Coordinator, Hepatitis C Treatment Panel				
Pharmac, PO Box 10-254, WELLINGTON Tel: (04) 460 4990	),			

Email: <u>hepcpanel@pharmac.govt.nz</u>

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

### **HIV Prophylaxis and Treatment**

EMTRICITABINE WITH TENOFOVIR DISOPROXIL – Subsidy by endorsement; can be waived by Special Authority see SA2138 below

- a) Funding for emtricitabine with tenofovir disoproxil for use as PrEP, should be applied using Special Authority SA2138.
- b) Endorsement for treatment of conditions approved via Special Authority SA2139 (antiretrovirals for confirmed HIV, prevention of maternal transmission, post-exposure prophylaxis following exposure to HIV and percutaneous exposure): Prescription is deemed to be endorsed if emtricitabine with tenofovir disoproxil is co-prescribed with another antiretroviral subsidised under Special Authority SA2139 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.

Note: Emtricitabine with tenofovir disoproxil prescribed under endorsement, for treatment of conditions approved via Special Authority SA2139 (antiretrovirals for confirmed HIV, prevention of maternal transmission, post-exposure prophylaxis following exposure to HIV and percutaneous exposure), is included in the count of up to 4 subsidised antiretrovirals, and counts as two antiretroviral medications, for the purposes of Special Authority SA2139, page 112 There is an approval process to become a named specialist to prescribe antiretroviral therapy in New Zealand. Further information is available on the Pharmac website.

\* Tab 200 mg with tenofovir disoproxil 245 mg (300 mg as a maleate)
13.45

	maleate)	Emtricitabine Viatr
*	Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a	
	succinate)	🗸 Teva

(Teva Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) to be delisted 1 August 2025)

#### ⇒SA2138 Special Authority for Subsidy

**Initial application** from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria: Both:

- 1 Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion; and
- 2 The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate.
- Notes: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines:

#### https://ashm.org.au/HIV/PrEP/

**Renewal** from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria: Both:

- 1 Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion; and
- 2 The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate.

Notes: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines:

https://ashm.org.au/HIV/PrEP/

### **COVID-19 Treatments**

NIRMATRELVIR WITH RITONAVIR - [Xpharm] - Subsidy by endorsement

- a) No patient co-payment payable
- b) Treatment is funded only if patient meets access criteria for oral antiviral COVID-19 treatments (as on <u>Pharmac's website</u>) and has been endorsed accordingly by the prescriber. The supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability.
  Teb 150 ma with iterative 100 ma

Tab 150 mg with ritonavir 100 mg ......0.00 30 🖌 Paxlovid

Subsidy		Fully	Brand or
(Manufacturer's Price)	5	Subsidised	Generic
`\$	Per	1	Manufacturer

# Antiretrovirals

#### ⇒SA2139 Special Authority for Subsidy

**Initial application** — (Confirmed HIV) only from a named specialist. Approvals valid without further renewal unless notified where the patient has confirmed HIV infection.

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

**Renewal** — (Confirmed HIV) only from a named specialist. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.

**Initial application — (Prevention of maternal transmission)** only from a named specialist. Approvals valid for 1 year for applications meeting the following criteria:

Either:

- 1 Prevention of maternal foetal transmission; or
- 2 Treatment of the newborn for up to eight weeks.

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Some antiretrovirals are unapproved or contraindicated for this indication. Practitioners prescribing these medications should exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of a Pharmaceutical for an indication for which it is not approved or contraindicated.

**Initial application** — (post-exposure prophylaxis following exposure to HIV) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Treatment course to be initiated within 72 hours post exposure; and
- 2 Any of the following:
  - 2.1 Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV positive person with an unknown or detectable viral load greater than 200 copies per ml; or
  - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
  - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required; or
  - 2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm.org.au/hiv/hiv-management/pep/).

Renewal — (second or subsequent post-exposure prophylaxis) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

- Both:
  - 1 Treatment course to be initiated within 72 hours post exposure; and
  - 2 Any of the following:
    - 2.1 Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV positive person

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

continued...

- with an unknown or detectable viral load greater than 200 copies per ml; or
- 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
- 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required; or
- 2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.

Initial application — (Percutaneous exposure) only from a named specialist. Approvals valid for 6 weeks where the patient has percutaneous exposure to blood known to be HIV positive.

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Renewal — (Second or subsequent percutaneous exposure) only from a named specialist. Approvals valid for 6 weeks where the patient has percutaneous exposure to blood known to be HIV positive.

### Non-nucleosides Reverse Transcriptase Inhibitors

EFAVIRENZ – Special Authority see SA2139 on the previous pa Note: No new patients to be initiated on efavirenz.	<mark>ige –</mark> Retail pha	rmacy	
Tab 600 mg	65.38	30	<ul> <li>Efavirenz</li> <li>Milpharm S29</li> </ul>
(Efavirenz Milpharm S29) Tab 600 mg to be delisted 1 Novembe	er 2026)		
ETRAVIRINE - Special Authority see SA2139 on the previous p	<mark>age</mark> – Retail pha	armacy	
Tab 200 mg	770.00	60	<ul> <li>Intelence</li> </ul>
NEVIRAPINE - Special Authority see SA2139 on the previous p	age – Retail ph	armacy	
Tab 200 mg	198.25	60	Nevirapine Viatris
Oral suspension 10 mg per ml	203.55	240 ml OP	<ul> <li>Viramune</li> <li>Suspension</li> </ul>

### **Nucleosides Reverse Transcriptase Inhibitors**

ABACAVIR SULPHATE – Special Authority see SA2139 on the previous page – Re Tab 300 mg	etail pharm 60	acy ✓ Ziagen
ABACAVIR SULPHATE WITH LAMIVUDINE – Special Authority see SA2139 on th Note: abacavir with lamivudine (combination tablets) counts as two anti-retrovir anti-retroviral Special Authority.		
Tab 600 mg with lamivudine 300 mg29.50	30	<ul> <li>Abacavir/ Lamivudine Viatris</li> </ul>
EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPROXIL – Special A Retail pharmacy Note: Efavirenz with emtricitabine and tenofovir disoproxil counts as three anti- anti-retroviral Special Authority	,	
Tab 600 mg with emtricitabine 200 mg and tenofovir disoproxil         245 mg (300 mg as a fumarate)	30	<ul> <li>TEEVIR \$29</li> <li>Triovir \$29</li> </ul>
Tab 600 mg with emtricitabine 200 mg and tenofovir disoproxil 245 mg (300 mg as a maleate)106.88	30	✓ Viatris
EMTRICITABINE – Special Authority see SA2139 on the previous page – Retail ph Cap 200 mg	armacy 30	<ul> <li>Emtriva</li> </ul>

▲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 Pr		Fully	Brand or Generic
	\$	Per		Manufacturer
LAMIVUDINE – Special Authority see SA2139 on page 112 –				
Tab 150 mg		60 0.40 ml OD		Lamivudine Viatris
Oral liq 10 mg per ml		240 ml OP	•	3TC
ZIDOVUDINE [AZT] – Special Authority see SA2139 on page		,		
Cap 100 mg		100	-	Retrovir
Oral liq 10 mg per ml		200 ml OP		Retrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority s Note: zidovudine [AZT] with lamivudine (combination table the anti-retroviral Special Authority.	ets) counts as two a		edica	tions for the purposes of
Tab 300 mg with lamivudine 150 mg	92.40	60	1	Lamivudine/ Zidovudine Viatris
Protease Inhibitors				
ATAZANAVIR SULPHATE - Special Authority see SA2139 on	page 112 - Retail	oharmacy		
Cap 150 mg		60	1	Atazanavir Mylan
			1	Atazanavir Viatris
Cap 200 mg (Atazanavir Mylan Cap 150 mg to be delisted 1 November 202		60	✓ .	Atazanavir Viatris
DARUNAVIR - Special Authority see SA2139 on page 112 - F	Retail pharmacy			
Tab 400 mg		60	1	Darunavir Viatris
Tab 600 mg		60	1	Darunavir Viatris
LOPINAVIR WITH RITONAVIR – Special Authority see SA213	39 on page 112 – Re	etail pharmacy		
Tab 100 mg with ritonavir 25 mg		60	•	Lopinavir/Ritonavir Mylan
Tab 200 mg with ritonavir 50 mg		120	1	Lopinavir/Ritonavir Mylan
RITONAVIR - Special Authority see SA2139 on page 112 - R	etail pharmacy			
Tab 100 mg		30	1	Norvir
Strand Transfer Inhibitors				
DOLUTEGRAVIR – Special Authority see SA2139 on page 11	2 – Retail pharmacy	/		
Tab 50 mg		30	1	Tivicay
DOLUTEGRAVIR WITH LAMIVUDINE – Special Authority see Tab 50 mg with lamivudine 300 mg		12 – Retail ph 30		cy Dovato
RALTEGRAVIR POTASSIUM – Special Authority see SA2139		ail pharmacy		
Tab 400 mg	1.0	60	1	Isentress
Tab 600 mg		60		Isentress HD

PEGYLATED INTERFERON ALFA-2A - Special Authority see SA2034 on the next page - Retail pharmacy 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 4

1.355.71

✓ Pegasys S29 S29

Subsidy		Fully	Brand or	
(Manufacturer's P	,	Subsidised	Generic	
\$	Per	1	Manufacturer	

#### ⇒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.

Renewal — (Chronic hepatitis C - genotype 1 infection) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Patient has chronic hepatitis C, genotype 1; and
- 2 Patient has had previous treatment with pegylated interferon and ribavirin; and
- 3 Either:
  - 3.1 Patient has responder relapsed; or
  - 3.2 Patient was a partial responder; and
- 4 Patient is to be treated in combination with boceprevir; and
- 5 Maximum of 48 weeks therapy.

Initial application — (Chronic Hepatitis C - genotype 1 infection treatment more than 4 years prior) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Patient has chronic hepatitis C, genotype 1; and
- 2 Patient has had previous treatment with pegylated interferon and ribavirin; and
- 3 Any of the following:
  - 3.1 Patient has responder relapsed; or
  - 3.2 Patient was a partial responder; or
  - 3.3 Patient received interferon treatment prior to 2004; and
- 4 Patient is to be treated in combination with boceprevir; and
- 5 Maximum of 48 weeks therapy.

Initial application — (chronic hepatitis C - genotype 2 or 3 infection without co-infection with HIV) from any specialist.

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

Both:

- 1 Patient has chronic hepatitis C, genotype 2 or 3 infection; and
- 2 Maximum of 6 months therapy.

**Initial application** — (Hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
- 2 Patient is Hepatitis B treatment-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

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

#### continued...

- 6 Compensated liver disease; and
- 7 No continuing alcohol abuse or intravenous drug use; and
- 8 Not co-infected with HCV, HIV or HDV; and
- 9 Neither ALT nor AST > 10 times upper limit of normal; and
- 10 No history of hypersensitivity or contraindications to pegylated interferon; and
- 11 Maximum of 48 weeks therapy.

**Initial application — (myeloproliferative disorder or cutaneous T cell lymphoma)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 Patient has a cutaneous T cell lymphoma\*; or
- 2 All of the following:
  - 2.1 Patient has a myeloproliferative disorder\*; and
  - 2.2 Patient is intolerant of hydroxyurea; and
  - 2.3 Treatment with anagrelide and busulfan is not clinically appropriate; or

3 Both:

- 3.1 Patient has a myeloproliferative disorder; and
- 3.2 Patient is pregnant, planning pregnancy or lactating.

# Renewal — (myeloproliferative disorder or cutaneous T cell lymphoma) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and patient is benefitting from treatment; and
- 3 Either:
  - 3.1 Patient has a cutaneous T cell lymphoma\*; or
  - 3.2 Both:
    - 3.2.1 Patient has a myeloproliferative disorder\*; and

3.2.2 Either:

- 3.2.2.1 Remains intolerant of hydroxyurea and treatment with anagrelide and busulfan remains clinically inappropriate; or
- 3.2.2.2 Patient is pregnant, planning pregnancy or lactating.

Note: Indications marked with \* are unapproved indications.

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**

🗸 UroFos

### ► SA2406 Special Authority for Subsidy

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

- 1 Patient has an acute, symptomatic, bacteriologically-proven uncomplicated urinary tract infection (UTI)/cystitis with Escherichia Coli; and
- 2 Either:

1

 e)	Fully Subsidised	Brand or Generic	
\$ Per	1	Manufacturer	

continued...

- 2.1 Microbiological testing confirms the pathogen is resistant to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin; or
- 2.2 The patient has a contraindication or intolerance to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin that the pathogen is susceptible to.

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

- 1 Patient has an acute, symptomatic, bacteriologically-proven uncomplicated urinary tract infection (UTI)/cystitis with Escherichia Coli; and
- 2 Either:
  - 2.1 Microbiological testing confirms the pathogen is resistant to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin; or
  - 2.2 The patient has a contraindication or intolerance to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin that the pathogen is susceptible to.

METHENAMINE (HEXAMINE) HIPPURATE			
* Tab 1 g	19.95	100	<ul> <li>Hiprex</li> </ul>
NITROFURANTOIN			
* Tab 50 mg – Up to 30 tab available on a PSO	22.20	100	<ul> <li><u>Nifuran</u></li> </ul>
* Tab 100 mg		100	<ul> <li>Nifuran</li> </ul>
* Cap modified-release 100 mg - Up to 15 cap available on a			
PSO		100	✓ Macrobid
NORFLOXACIN			
Tab 400 mg - Subsidy by endorsement		100	Arrow-Norfloxacin

# MUSCULOSKELETAL SYSTEM

	0.1.11		
	Subsidy (Manufacturer's Price	) <u>Su</u>	Fully Brand or bsidised Generic
	(Manulacialer ST files	Per	✓ Manufacturer
Anticholinesterases			
NEOSTIGMINE METILSULFATE			
Inj 2.5 mg per ml, 1 ml ampoule	48.25	10	<ul> <li>Max Health</li> </ul>
PYRIDOSTIGMINE BROMIDE			<u></u>
▲ Tab 60 mg	50.29	100	✓ Mestinon
Tab 60 mg		100	• Mestinon
Non-Steroidal Anti-Inflammatory Drugs			
	0.10	50	
* Tab EC 25 mg		50 20	<ul> <li>✓ <u>Diclofenac Sandoz</u></li> <li>✓ Voltaren D</li> </ul>
* Tab 50 mg dispersible		20 50	<ul> <li>Voltaren D</li> <li>✓ Diclofenac Sandoz</li> </ul>
* Tab EC 50 mg		100	✓ Voltaren SR
Tab long-acting 75 mg Voltaren SR to be Principal Supply on 1 August 2025		100	
<ul> <li>Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a F</li> </ul>	PSO 13.20	5	✓ Voltaren
* Suppos 12.5 mg		10	✓ Voltaren
* Suppos 25 mg		10	✓ Voltaren
<ul> <li>Suppos 20 mg – Up to 10 supp available on a PSO</li> </ul>		10	✓ Voltaren
* Suppos 100 mg		10	✓ Voltaren
BUPROFEN			
BOFROFEN * Tab 200 mg	21.40	1.000	✓ Relieve
★ Tab 200 mg		30	✓ Ibuprofen SR BNM
<ul> <li>Tab long-acting 800 mg</li> <li>Washing acting 800 mg</li> <li>Oral lig 20 mg per ml</li> </ul>		200 ml	✓ Ethics
	2.05	200 111	• <u>Eunes</u>
KETOPROFEN	40.07	~~	
* Cap long-acting 200 mg		28	<ul> <li>Oruvail SR</li> </ul>
MEFENAMIC ACID			
* Cap 250 mg	1.25	50	
	(10.82)		Ponstan
	0.50	20	_
	(7.50)		Ponstan
NAPROXEN			
卷 Таb 250 mg		500	<ul> <li><u>Noflam 250</u></li> </ul>
* Tab 500 mg	34.45	250	<ul> <li><u>Noflam 500</u></li> </ul>
* Tab long-acting 750 mg	10.40	28	<ul> <li>Naprosyn SR 750</li> </ul>
* Tab long-acting 1 g	11.50	28	Naprosyn SR 1000
TENOXICAM			
* Tab 20 mg		100	✓ Tilcotil
* Inj 20 mg vial	9.95	1	🗸 AFT
NSAIDs Other			
CELECOXIB			
Cap 100 mg	3.45	60	<ul> <li>Celebrex</li> </ul>
			<ul> <li>Celecoxib Pfizer</li> </ul>
Cap 200 mg	3.20	30	<ul> <li>Celebrex</li> </ul>
			<ul> <li>Celecoxib Pfizer</li> </ul>

#### Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per Manufacturer **Topical Products for Joint and Muscular Pain** CAPSAICIN Crm 0.025% - Special Authority see SA1289 below - Retail 45 a OP ✓ Zo-Rub Osteo S29 ✓ Zostrix ➡SA1289 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has osteoarthritis that is not responsive to paracetamol and oral non-steroidal anti-inflammatories are contraindicated. Antirheumatoid Agents HYDROXYCHLOROQUINE SULPHATE - Brand switch fee payable (Pharmacode 2704676) - see page 281 for details Ipca-100 Hvdroxvchloroquine LEFLUNOMIDE Arava 30 \* Tab 20 mg ......6.00 30 Arava PENICILLAMINE 100 ✓ D-Penamine 100 D-Penamine Drugs Affecting Bone Metabolism Alendronate for Osteoporosis ALENDRONATE SODIUM Fosamax ALENDRONATE SODIUM WITH COLECALCIFEROL Tab 70 mg with colecalciferol 5,600 iu ......1.99 Fosamax Plus 4 Other Treatments DENOSUMAB - Special Authority see SA2441 below - Retail pharmacy Note: Denosumab ini 60 mg per 1 ml pre-filled syringe is Medsafe approved for use in osteoporosis. Denosumab ini 120 mg per 1.7 ml vial is Medsafe approved for use in hypercalcaemia of malignancy. ✓ Xgeva 1 1 ✓ Prolia ⇒SA2441 Special Authority for Subsidy Initial application - (Osteoporosis) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria: All of the following: 1 The patient has established osteoporosis; and 2 Any of the following: 2.1 History of one significant osteoporotic fracture demonstrated radiologically, with a documented T-Score less than or equal to -2.5, that incorporates BMD measured using dual-energy x-ray absorptiometry (DEXA); or

MUSCULOSKELETAL SYSTEM

2.2 History of one significant osteoporotic fracture, demonstrated radiologically, and either the patient is elderly, or

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

#### continued...

- densitometry scanning cannot be performed because of logistical, technical or pathophysiological reasons; or
- 2.3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 2.4 Documented T-Score less than or equal to -3.0; or
- 2.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm that incorporates BMD measured using DEXA; and

#### 3 Any of the following:

- 3.1 Bisphosphonates are contraindicated because the patient's creatinine clearance or eGFR is less than 35 mL/min; or
- 3.2 The patient has experienced at least two symptomatic new fractures or a BMD loss greater than 2% per year, after at least 12 months' continuous therapy with a funded antiresorptive agent; or
- 3.3 Bisphosphonates result in intolerable side effects; or
- 3.4 Intravenous bisphosphonates cannot be administered due to logistical or technical reasons.

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

Both:

R \*

- 1 Patient has hypercalcaemia of malignancy; and
- 2 Patient has severe renal impairment.

#### PAMIDRONATE DISODIUM

Inj 3 mg per ml, 10 ml vial					
Inj 6 mg per ml, 10 ml vial 88.11 1 • Pamiso	J				
Inj 9 mg per ml, 10 ml vial 94.34 1 • Pamiso	J				
RALOXIFENE HYDROCHLORIDE – Special Authority see SA1779 below – Retail pharmacy					
★ Tab 60 mg					

#### ⇒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

### MUSCULOSKELETAL SYSTEM

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

continued...

definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.

d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

#### RISEDRONATE SODIUM

Tab 35 mg2.50	4	<ul> <li>Risedronate Sandoz</li> </ul>
TERIPARATIDE – Special Authority see SA1139 below – Retail pharmacy		
Inj 250 mcg per ml, 2.4 ml	1	🗸 Teriparatide - Teva

#### ⇒SA1139 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 18 months for applications meeting the following criteria: All of the following:

- 1 The patient has severe, established osteoporosis; and
- 2 The patient has a documented T-score less than or equal to -3.0 (see Notes); and
- 3 The patient has had two or more fractures due to minimal trauma; and
- 4 The patient has experienced at least one symptomatic new fracture after at least 12 months' continuous therapy with a funded antiresorptive agent at adequate doses (see Notes).

Notes:

- a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable
- b) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: alendronate sodium tab 70 mg or tab 70 mg with colecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy.
- c) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
- d) A maximum of 18 months of treatment (18 cartridges) will be subsidised.

ZOLEDRONIC ACID Inj 0.05 mg per ml, 100 ml, bag	22.53	1	<ul> <li>Zoledronic Acid Viatris</li> </ul>
Hyperuricaemia and Antigout			
ALLOPURINOL	17 99	1 000	Inca-Allonurinol

* Tab 300 mg	,	✓ <u>Ipca-Allopurinol</u>
BENZBROMARONE - Special Authority see SA1963 below -	- Retail pharmacy	
Tab 50 mg		<ul> <li>Narcaricin mite S29</li> </ul>

#### ⇒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.

### MUSCULOSKELETAL SYSTEM

(	Subsidy (Manufacturer's Price) \$		Fully Subsidised	Brand or Generic Manufacturer
COLCHICINE * Tab 500 mcg	6.00	100	•	Colgout
FEBUXOSTAT - Special Authority see SA2054 below - Retail pha	,			<b>-</b>
Tab 80 mg Tab 120 mg		28 28	-	<u>Febuxostat (Teva)</u> Febuxostat (Teva)

#### ⇒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..

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.

PROBENECID		
* Tab 500 mg66.95	100	Probenecid-AFT

### **Muscle Relaxants**

BACLOFEN	
----------	--

<ul> <li>Tab 10 mg</li> <li>Inj 0.05 mg per ml, 1 ml ampoule – Subsidy by endorsement</li> <li>Subsidised only for use in a programmable pump in patients caused intolerable side effects and the prescription is endorsed and the prescription is endorsed.</li> </ul>	11.55 where oral anti		<ul> <li><u>Pacifen</u></li> <li>Lioresal Intrathecal ents have been ineffective or have</li> </ul>
Inj 2 mg per ml, 5 ml ampoule – Subsidy by endorsement		10	<ul> <li><u>Sintetica Baclofen</u></li> <li><u>Intrathecal</u></li> </ul>
Subsidised only for use in a programmable pump in patients caused intolerable side effects and the prescription is endors			ents have been ineffective or have
DANTROLENE			
Cap 25 mg	145.77	100	<ul> <li>Dantrium S29 S29</li> </ul>
Cap 50 mg	77.00	100	<ul> <li>Dantrium</li> </ul>
ORPHENADRINE CITRATE			
Tab 100 mg	23.25	100	✓ <u>Norflex</u>

	Subsidy		Fully Bran	
	(Manufacturer's Price) \$	Per	Subsidised Gene Man	ric ifacturer
Agents for Parkinsonism and Related Disorders	;			
Dopamine Agonists and Related Agents				
AMANTADINE HYDROCHLORIDE				
▲ Cap 100 mg		60	<ul> <li>Symme</li> </ul>	
	63.73	100	<ul> <li>Symme</li> </ul>	trel
APOMORPHINE HYDROCHLORIDE	50 50	_	<i>.</i>	
▲ Inj 10 mg per ml, 2 ml ampoule		5	<ul> <li>Movapo</li> </ul>	
▲ Inj 10 mg per ml, 5 ml ampoule	121.84	5	<ul> <li>Movapo</li> </ul>	)
	10.70	100		Mistria
▲ Tab 200 mg	13.73	100	• Entaca	oone Viatris
LEVODOPA WITH BENSERAZIDE			<i>.</i>	
* Tab dispersible 50 mg with benserazide 12.5 mg		100	<ul> <li>Madopa</li> <li>Madopa</li> </ul>	•
Cap 50 mg with benserazide 12.5 mg		100 100	✓ Madopa	
<ul> <li>Cap 100 mg with benserazide 25 mg</li> <li>Cap long-acting 100 mg with benserazide 25 mg</li> </ul>		100	<ul> <li>✓ Madopa</li> <li>✓ Madopa</li> </ul>	
<ul> <li>Cap long-acting roo mg with benserazide 50 mg</li> <li>Cap 200 mg with benserazide 50 mg</li> </ul>		100	<ul> <li>Madopa</li> <li>Madopa</li> </ul>	
LEVODOPA WITH CARBIDOPA		100	induop	
* Tab 100 mg with carbidopa 25 mg	26.40	100	<ul> <li>Sineme</li> </ul>	•
<ul> <li>Tab long-acting 200 mg with carbidopa 50 mg</li> </ul>		100	✓ Sineme	
<ul> <li>Tab 250 mg with carbidopa 25 mg</li> </ul>		100	✓ Sineme	
LEVODOPA WITH CARBIDOPA AND ENTACAPONE				-
* Tab 50 mg with carbidopa 12.5 mg and entacapone 200 mg	27 01	100	<ul> <li>Stalevo</li> </ul>	
* Tab 100 mg with carbidopa 25 mg and entacapone 200 mg .		100	✓ Stalevo	
* Tab 150 mg with carbidopa 37.5 mg and entacapone 200 mg		100	✓ Stalevo	
* Tab 200 mg with carbidopa 50 mg and entacapone 200 mg.		100	✓ Stalevo	
PRAMIPEXOLE HYDROCHLORIDE				
▲ Tab 0.25 mg	5.23	100	🗸 Ramipe	x
▲ Tab 1 mg	17.73	100	<ul> <li>Ramipe</li> </ul>	x
RASAGILINE				
* Tab 1 mg		30	<ul> <li>Azilect</li> </ul>	S29
ROPINIROLE HYDROCHLORIDE				
▲ Tab 0.25 mg	4.05	84	🗸 Ropin	
▲ Tab 1 mg		84	🗸 Ropin	
▲ Tab 2 mg	6.48	84	🗸 Ropin	
▲ Tab 5 mg	14.50	84	🗸 Ropin	
TOLCAPONE				
▲ Tab 100 mg		100	🗸 Tasmar	
Anticholinergics				
BENZATROPINE MESYLATE				
Tab 2 mg	9.59	60	✓ Benztro	a
Inj 1 mg per ml, 2 ml.		5	✓ Denzire	•
<ul> <li>a) Up to 10 inj available on a PSO</li> <li>b) Only on a PSO</li> </ul>		U	- 110014	
PROCYCLIDINE HYDROCHLORIDE				
Tab 5 mg		100	🗸 Kemad	rin
· · · · g			Konnuu	

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

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

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	) Sub Per	Fully osidised	Brand or Generic Manufacturer
Agents for Essential Tremor, Chorea and Re	elated Disorders			
RILUZOLE – Special Authority see SA1403 below – Retail p Wastage claimable	bharmacy			
Tab 50 mg	117.00	56	✓ <u>R</u>	lilutek
SA1403 Special Authority for Subsidy				
nitial application only from a neurologist or respiratory spe	cialist. Approvals valid for	or 6 month	is for app	plications meeting the
bllowing criteria:				
Il of the following:			1	
<ol> <li>The patient has amyotrophic lateral sclerosis with dis</li> <li>The patient has at least 60 percent of predicted force</li> <li>The patient has not undergone a tracheostomy; and</li> <li>The patient has not experienced respiratory failure; a</li> <li>Any of the following:</li> </ol>	d vital capacity within 2 n			initial application; and
5.1 The patient is ambulatory; or				
5.2 The patient is able to use upper limbs; or				
5.3 The patient is able to swallow.				
Renewal from any relevant practitioner. Approvals valid for In of the following:	18 months for application	ns meeting	the follo	owing criteria:
1 The patient has not undergone a tracheostomy; and				
<ul> <li>2 The patient has not experienced respiratory failure; a</li> <li>3 Any of the following:</li> </ul>	nd			
3.1 The patient is ambulatory; or				
3.2 The patient is able to use upper limbs; or				
3.3 The patient is able to swallow.				
FETRABENAZINE				
Tab 25 mg	106.59	112	🗸 N	lotetis
Anaesthetics				
Local				
IDOCAINE [LIGNOCAINE]				
Gel 2%, tube – Subsidy by endorsement	14.50	30 ml	✓ X	ylocaine 2% Jelly
a) Up to 150 ml available on a PSO	ical administration and th	o proco-i-	tion in a	adaraad accordinate
<ul> <li>b) Subsidised only if prescribed for urethral or cerv</li> <li>Gel 2%, 11 ml urethral syringe – Subsidy by endorseme</li> <li>a) Up to 5 each available on a PSO</li> </ul>		e prescrip 10		ndorsed accordingly. Istillagel Lido
b) Subsidised only if prescribed for urethral, cervica	al or rectal administration	and the p	rescriptio	on is endorsed

 b) Subsidised only if prescribed for urethral, cervical or rectal administration and the prescription is endorsed accordingly.

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	) Subs	idised	Generic
	\$	Per	1	Manufacturer
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE				
Oral (gel) soln 2%		200 ml		Mucosoothe
Inj 1%, 5 ml ampoule - Up to 25 inj available on a PSO		25	✓	Lidocaine-Baxter
	17.50	50		
	(35.00)			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		5		Lidocaine-Baxter
Inj 2%, 20 ml vial - Up to 5 inj available on a PSO		5	<ul> <li>Image: A second s</li></ul>	Lidocaine-Baxter
Inj 10%, 5 ml ampoule - Subsidy by endorsement		10		Xylocard 500 S29
Subsidised only for people receiving palliative care serv	ices where other ana	Igesic ager	nts hav	/en't been effective.

### **Topical Local Anaesthetics**

### ► SA0906 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years where the patient is a child with a chronic medical condition requiring frequent injections or venepuncture.

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

LIDOCAINE [LIGNOCAINE] – Special Authority see SA0906 a	above – Retail pharr	nacy	
Crm 4%	5.40	5 g OP	🖌 LMX4
	27.00	30 g OP	🖌 LMX4
LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE - Special Au	uthority see SA0906	above - Reta	il pharmacy
Crm 2.5% with prilocaine 2.5%		30 g OP	🖌 EMLA
Crm 2.5% with prilocaine 2.5% (5 g tubes)	45.00	5	🖌 EMLA

### Analgesics

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 118

### **Non-opioid Analgesics**

ASPIRIN * Tab dispersible 300 mg – Up to 30 tab available on a PSO5.65	100	✓ Ethics Aspirin
CAPSAICIN – Subsidy by endorsement		
Subsidised only if prescribed for post-herpetic neuralgia or diabetic periphera accordingly.	I neuropathy a	nd the prescription is endorsed
Crm 0.075%11.95	45 g OP	<ul> <li>✓ Zo-Rub HP \$29</li> <li>✓ Zostrix HP</li> </ul>
NEFOPAM HYDROCHLORIDE		
Tab 30 mg23.40	90	<ul> <li>Acupan</li> </ul>

	Subsidy Fully Brand or
	(Manufacturer's Price) Subsidised Generic
	\$ Per 🖌 Manufacturer
PARACETAMOL	
Tab 500 mg - blister pack	
<ul> <li>a) Maximum of 300 tab per prescription; can be v</li> </ul>	vaived by endorsement
<li>b) Up to 30 tab available on a PSO</li>	
c)	
	tities is available for patients with long term conditions who require
	eater, and the prescription is annotated accordingly. Pharmacists may here dispensing history supports a long-term condition.
	non-endorsed patients. If quantities prescribed for more than 100 tabs
	se in repeat dispensings not exceeding 100 tab per dispensing.
Tab 500 mg - bottle pack – Maximum of 300 tab per	se in repeat disperion ge net exceeding roo tas per disperion g.
prescription; can be waived by endorsement	
······································	Paracetamol
1) Subsidy by endorsement for higher quantitie	es is available for patients with long term conditions who require regular
	he prescription is annotated accordingly. Pharmacists may annotate the
prescription as endorsed where dispensing	
	endorsed patients. If quantities prescribed for more than 100 tabs (for
non-endorsed patients), then dispense in re	peat dispensings not exceeding 100 tab per dispensing.
Oral liq 120 mg per 5 ml	
	(Ethics)
a) Maximum of 600 ml per prescription; can be w	aived by endorsement
<ul><li>b) Up to 200 ml available on a PSO</li><li>c) Not in combination</li></ul>	
d)	
,	on-endorsed patients. If quantities prescribed exceed 200 ml (for
	repeat dispensing not exceeding 200 ml per dispensing.
	tities is available for patients with long term conditions who require
	eater and the prescription is endorsed or annotated accordingly.
	on as endorsed where dispensing history supports a long-term
condition.	
	nol oral liquid may be supplied on BSO to a Vaccinator (other than a
Pharmacist) under the provisions in Part	of up to 200 ml permitted under the provisions in Part I of Section A in
conjunction with immunisation of a child	under 2 years of age with meningococcal B multicomponent vaccine.
Oral lig 250 mg per 5 ml	
a) Maximum of 600 ml per prescription; can be w	
b) Up to 200 ml available on a PSO	·
c) Not in combination	
d)	
	on-endorsed patients. If quantities prescribed exceed 200 ml (for
	n repeat dispensing not exceeding 200 ml per dispensing.
	tities is available for patients with long term conditions who require
	eater and the prescription is endorsed or annotated accordingly. on as endorsed where dispensing history supports a long-term
condition.	on as shadrood where depending history supports a long term
	nol oral liquid may be supplied on BSO to a Vaccinator (other than a
Pharmacist) under the provisions in Part	
	of up to 200 ml permitted under the provisions in Part I of Section A in
	under 2 years of age with meningococcal B multicomponent vaccine.
* Suppos 125 mg	

_					
		Subsidy		Fully	
		(Manufacturer's Price)	_	Subsidised	
_		\$	Per		Manufacturer
*	Suppos 250 mg	5.39	10	1	Gacet
*	Suppos 500 mg		50	✓	Gacet
C	pioid Analgesics				
CC	DEINE PHOSPHATE – Safety medicine; prescriber may dete	rmine dispensing fre	quen	су	
	Tab 15 mg	5.82	100	✓	Noumed
	Tab 30 mg		100	✓	Noumed
	Tab 60 mg		100	✓	Noumed
DIF	IYDROCODEINE TARTRATE				
	Tab long-acting 60 mg	8.60	60	1	DHC Continus
	NTANYL				
٢Ē					
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fre		40		Development Made
	Inj 50 mcg per ml, 2 ml ampoule		10		Boucher and Muir
	Inj 50 mcg per ml, 10 ml ampoule		10	-	Boucher and Muir
	Patch 12 mcg per hour		5		Fentanyl Sandoz
	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		5	~	Fentanyl Sandoz
(Fe	ntanyl Sandoz Patch 12.5 mcg per hour to be delisted 1 Nove	mber 2025)			
ME	THADONE HYDROCHLORIDE				
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fre	auencv			
	Tab 5 mg		10	1	Methadone BNM
	Oral lig 2 mg per ml		200 m	nl 🗸	Biodone
	Oral lig 5 mg per ml		200 m	nl 🗸	Biodone Forte
	Oral lig 10 mg per ml		200 m		Biodone Extra Forte
	lnj 10 mg per ml, 1 ml		10		AFT
мс	PRPHINE HYDROCHLORIDE				
IVIC					
	a) Only on a controlled drug form				
	<ul> <li>b) No patient co-payment payable</li> <li>c) Sofaty medicine: prescriber may determine dispensing from the second seco</li></ul>	auonov.			
	c) Safety medicine; prescriber may determine dispensing fre		<u>م</u> م ~	al ./	DA Morph
	Oral liq 1 mg per ml		200 m	-	RA-Morph
	Oral liq 2 mg per ml		200 m		RA-Morph
	Oral liq 5 mg per ml		200 m		RA-Morph
	Oral liq 10 mg per ml		200 m	n 🗸	RA-Morph

	Subsidy		Fully	Brand or
	(Manufacturer's Price \$	e) Sul Per	osidised	Generic Manufacturer
	φ	FEI	•	Manufacturer
ORPHINE SULPHATE				
a) Only on a controlled drug form				
<ul> <li>b) No patient co-payment payable</li> <li>c) Sofati medicinal properties dispension from</li> </ul>	~~~~~			
c) Safety medicine; prescriber may determine dispensing free		10		Sevredol
Tab immediate-release 10 mg Tab immediate-release 20 mg		10		Sevredol
Cap long-acting 10 mg		10		m-Eslon
Cap long-acting 30 mg		10		m-Eslon
Cap long-acting 50 mg		10		m-Eslon
Cap long-acting 100 mg		10		m-Eslon
Oral lig 2 mg per ml		100 ml		Wockhardt S29
Oran iiq 2 mg per mi	29.80	100 111		Oramorph
	29.00			Oramorph CDC
			•	
	0 5 00	-		S29 S29
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PS		5		Medsurge
Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a P		5		Medsurge
Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a P		5		Medsurge
Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a PS	50 6.28	5	<b>v</b>	Medsurge
(YCODONE HYDROCHLORIDE				
<ul> <li>a) Only on a controlled drug form</li> </ul>				
<ul> <li>b) No patient co-payment payable</li> </ul>				
c) Safety medicine; prescriber may determine dispensing free				
Tab controlled-release 5 mg		20		Oxycodone Sandoz
Tab immediate-release 5 mg		100		Oxycodone Amneal
Tab controlled-release 10 mg		20		Oxycodone Sandoz
Tab immediate-release 10 mg		100		Oxycodone Amneal
Tab controlled-release 20 mg		20		Oxycodone Sandoz
Tab immediate-release 20 mg		100		Oxycodone Amneal
Tab controlled-release 40 mg		20		Oxycodone Sandoz
Tab controlled-release 80 mg		20		Oxycodone Sandoz
Oral liq 1 mg per ml		250 ml		Oxycodone Lucis
Inj 10 mg per ml, 1 ml ampoule		5	-	Hameln
Inj 10 mg per ml, 2 ml ampoule		5		Hameln
Inj 50 mg per ml, 1 ml ampoule		5		Hameln
RACETAMOL WITH CODEINE – Safety medicine; prescriber	may determine dis	pensing fre		
Tab paracetamol 500 mg with codeine phosphate 8 mg	27.50	1,000	✓ 1	Paracetamol +
				Codeine (Relieve)
THIDINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing free	quency			
Tab 50 mg		10	✓	Noumed Pethidine
Inj 50 mg per ml, 1 ml ampoule - Up to 5 inj available on a PS		5	✓	DBL Pethidine
Jee Ster Ster Ster Ster Ster Ster Ster St				Hydrochloride
Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a P	SO30.72	5	<b>√</b>	DBL Pethidine
		÷		Hydrochloride
RAMADOL HYDROCHLORIDE				,
Tab sustained-release 100 mg	1 05	20	1.	Tramal SR 100
Tab sustained-release 100 mg		20		Tramal SR 150
Tab sustained-release 200 mg		20	-	Tramal SR 200
Cap 50 mg		100		Arrow-Tramadol
oup oo my		100	• !	

fully subsidised
 Principal Supply

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			NEH	VOUS SYSTEM
	Subsidy (Manufacturer's Price) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer
Antidepressants				
Cyclic and Related Agents				
AMITRIPTYLINE - Safety medicine; prescriber may determ				
Tab 10 mg		100		Arrow-Amitriptyline
Tab 25 mg Tab 50 mg		100 100		Arrow-Amitriptyline Arrow-Amitriptyline
•			-	
CLOMIPRAMINE HYDROCHLORIDE – Safety medicine; pr Tab 25 mg		50		APO Clomipramine
Cap 10 mg		28		Clomipramine Teva
(Clomipramine Teva Cap 10 mg to be delisted 1 April 2026)		20		
DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE – Subsidy b	v endorsement			
<ul> <li>a) Safety medicine; prescriber may determine dispensir</li> <li>b) Subsidy by endorsement – Subsidised for patients w 2019 and the prescription is endorsed accordingly. F exists a record of prior dispensing of dosulepin [dothing]</li> <li>Tab 75 mg</li> </ul>	ng frequency ho were taking dosulepin Pharmacists may annotate epin] hydrochloride.		scription	
Cap 25 mg		30 50		Dosulepin
Oap 20 mg		50	• •	Viatris S29
	ihar may datarmina diana	noina fre		
IMIPRAMINE HYDROCHLORIDE – Safety medicine; presci Tab 10 mg		50		ofranil
Tab To Tig	10.96	100		ofranil
Tab 25 mg		28	-	mipramine
				Crescent S29
	8.80	50	🗸 1	Tofranil
NORTRIPTYLINE HYDROCHLORIDE – Safety medicine; p	rescriber may determine o	dispensir	na freaue	encv
Tab 10 mg		100		Vorpress
Tab 25 mg		180		lorpress
Monoamine-Oxidase Inhibitors (MAOIs) - No	n Selective			
TRANYLCYPROMINE SULPHATE				
* Tab 10 mg	22.94	50	🖌 F	Parnate
Monoamine-Oxidase Type A Inhibitors				
MOCLOBEMIDE				
* Tab 150 mg	23.60	60	<b>1</b>	Aurorix
* Tab 300 mg		60		Aurorix
ů.		00	· ·	
Selective Serotonin Reuptake Inhibitors				
CITALOPRAM HYDROBROMIDE				
* Tab 20 mg	2.86	84	✓ (	Celapram
ESCITALOPRAM			_	
* Tab 10 mg		28		pca-Escitalopram
	1.07		✓ E	Escitalopram
* T-h 00 mm	1.40	00		(Ethics)
* Tab 20 mg	1.49	28	<b>√</b> [	pca-Escitalopram

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

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

NERVOUS SYSTEM

	0.4			Durandina
	Subsidy (Manufacturer's Price)		Fully Subsidised	
	(International Contents Fride)	Per		Manufacturer
LUOXETINE HYDROCHLORIDE	*			
Tab dispersible 20 mg, scored - Subsidy by endorsement	2.50	28	1	Fluox
Subsidised by endorsement				
<ol> <li>When prescribed for a patient who cannot swallow v accordingly; or</li> </ol>	whole tablets or cap	sules	and the pr	escription is endorsed
<ol> <li>When prescribed in a daily dose that is not a multipl endorsed. Note: Tablets should be combined with</li> </ol>				
endorsed. Note. Tablets should be combined with				Ũ
- Cap 20 mg	3.13	90	1	Arrow-Fluoxetine
AROXETINE				
F Tab 20 mg	4.11	90	1	Loxamine
ERTRALINE				
<ul> <li>Tab 50 mg</li> </ul>	0.99	30		Setrona
• Tab 100 mg	1.74	30	~	Setrona
Other Antidepressants				
IIRTAZAPINE				
Tab 30 mg	2.60	30	✓	Noumed
Tab 45 mg	3.45	30	✓	Noumed
ENLAFAXINE				
€ Cap 37.5 mg		84	✓	Enlafax XR
Cap 75 mg		84	✓	Enlafax XR
Cap 150 mg	13.95	84	1	Enlafax XR
Antiepilepsy Drugs				
Agents for Control of Status Epilepticus				
IAZEPAM - Safety medicine; prescriber may determine dispens				
Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement	27.92	5	<b>~</b>	Hospira
a) Up to 5 inj available on a PSO				
b) Only on a PSO				
c) PSO must be endorsed "not for anaesthetic procedure		_		<b>•</b>
Rectal tubes 5 mg – Up to 5 tube available on a PSO	54.58	5	~	Stesolid
HENYTOIN SODIUM				
Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a	1015-	-	-	
PSO	104.58	5	~	Hospira
Inj 50 mg per ml, 5 ml ampoule – Up to 5 inj available on a PSO	154.01	5		Hoopiro
Hospira Inj 50 mg per ml, 2 ml ampoule to be delisted 1 February		5	•	Hospira
Control of Epilepsy	-/			
		100		Togratal
	14 50	100		Tegretol
ARBAMAZEPINE ≰ Tab 200 mg	14.53		_	
€ Tab 200 mg				Tegretol AU
	16.98	100	1	Tegretol CR
<ul> <li>Tab 200 mg</li> <li>Tab long-acting 200 mg</li> </ul>	16.98 33.96	100 200	/ /	Tegretol CR Tegretol CR
<ul> <li>Tab 200 mg</li> <li>Tab long-acting 200 mg</li> <li>Tab 400 mg</li> </ul>		100 200 100	\$ \$ \$	Tegretol CR Tegretol CR Tegretol
Tab 200 mg     Tab long-acting 200 mg		100 200	\$ \$ \$ \$ \$	Tegretol CR Tegretol CR

130 ✓ fully subsidised Principal Supply (\$29) Unapproved medicine supplied under Section 29 Sole Subsidised Supply

	Subsidy		Fully	Brand or
	(Manufacturer's Pric	Per Subs	sidised	Generic
	\$	Per	/	Manufacturer
CLOBAZAM - Safety medicine; prescriber may determine dispe	nsing frequency			
Tab 10 mg	9.12	50	🗸 F	risium
CLONAZEPAM - Safety medicine; prescriber may determine dis	spensing frequency	/		
Oral drops 2.5 mg per ml	7.38	10 ml OP	🗸 F	Rivotril
ETHOSUXIMIDE				
Cap 250 mg		56	✓ E	ssential
				Ethosuximide S29
	140.88	100	√ z	arontin
Oral lig 250 mg per 5 ml		200 ml	✓z	arontin
(Essential Ethosuximide S29) Cap 250 mg to be delisted 1 Dece	mber 2025)			
GABAPENTIN				
Note: Not subsidised in combination with subsidised pregab	alin			
* Cap 100 mg		100	<b>/</b> N	lupentin
* Cap 300 mg		100	-	lupentin
* Cap 400 mg		100	-	lupentin
		100	• •	upentin
LACOSAMIDE – Special Authority see SA2267 below – Retail p				<i>.</i> .
▲ Tab 50 mg		14		/impat
▲ Tab 100 mg		14		/impat
	200.24	56		/impat
▲ Tab 150 mg		14		/impat
	300.40	56		/impat
▲ Tab 200 mg		56	<ul> <li></li> </ul>	/impat

#### SA2267 Special Authority for Subsidy

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

- 1 Patient has focal epilepsy; and
- 2 Seizures are not adequately controlled by, or patient has experienced unacceptable side effects from, optimal treatment with all of the following: sodium valproate, topiramate, levetiracetam and any two of carbamazepine, lamotrigine and phenytoin sodium (see Note).

Note: Those of childbearing potential are not required to trial phenytoin sodium, sodium valproate, or topiramate. Those who can father children are not required to trial 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.

▲ Tab dispersible 2 mg		30	<ul> <li>Lamictal</li> </ul>
▲ Tab dispersible 5 mg		30	<ul> <li>Lamictal</li> </ul>
* Tab dispersible 25 mg	4.20	56	<ul> <li>Logem</li> </ul>
* Tab dispersible 50 mg	5.11	56	<ul> <li>Logem</li> </ul>
* Tab dispersible 100 mg	6.75	56	<ul> <li>Logem</li> </ul>
LEVETIRACETAM			
Tab 250 mg	5.84	60	<ul> <li>Everet</li> </ul>
Tab 500 mg		60	<ul> <li>Everet</li> </ul>
Tab 750 mg		60	<ul> <li>Everet</li> </ul>
Tab 1,000 mg	21.82	60	<ul> <li>Everet</li> </ul>
Oral liq 100 mg per ml		300 ml OP	Levetiracetam-AFT
Inj 100 mg per ml, 5 ml vial		10	<ul> <li>Levetiracetam-AFT</li> </ul>

	Subsidy		Fully	
	(Manufacturer's Price \$	e) S Per	Subsidised	Generic Manufacturer
PHENOBARBITONE	Ŷ		-	manarataron
For phenobarbitone oral liquid refer Standard Formula	282 0000 0			
Tab 15 mg		500	1	Noumed
140 10 mg	240.00	000	•	Phenobarbitone
Tab 30 mg	398 50	500	1	Noumed
		000	•	Phenobarbitone
PHENYTOIN SODIUM				1 Honobal bitono
K Tab 50 mg	75.00	200	1	Dilantin Infatab
Cap 30 mg		200		Dilantin
Cap 30 mg		200		Dilantin
* Oral lig 30 mg per 5 ml		500 ml		Dilantin Paediatric
PREGABALIN		000 111	•	Bhanan i acaiaano
	achonontin			
Note: Not subsidised in combination with subsidised Cap 25 mg		56		Lyrica
<del>*</del> Сар 25 mg		50		Pregabalin Pfizer
₭ Cap 75 mg	2.65	56		Lyrica
* Oap 75 mg	2.05	50		Pregabalin Pfizer
* Cap 150 mg	4 01	56		Lyrica
		00		Pregabalin Pfizer
* Cap 300 mg	7 38	56		Lyrica
		00		Pregabalin Pfizer
PRIMIDONE				
* Tab 250 mg	37 35	100	1	Primidone Clinect
0		100	•	
SODIUM VALPROATE	40.05	100		Fulling Ormalishing
Tab 100 mg		100		Epilim Crushable
Tab 200 mg EC		100		Epilim
Tab 500 mg EC		100 300 ml		Epilim Epilim S/E Liquid
* Oral liq 200 mg per 5 ml	20.48	300 mi		Epilim S/F Liquid Epilim Syrup
* Inj 100 mg per ml, 4 ml	41 50	1		Epilim IV
		1	•	
STIRIPENTOL – Special Authority see SA2268 below – I		~~		Dia
Cap 250 mg		60		Diacomit
Powder for oral liq 250 mg sachet		60	•	Diacomit

#### ⇒SA2268 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.

Note: Those of childbearing potential are not required to trial sodium valproate or topiramate. Those who can father children are not required to trial sodium valproate.

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.

	Subsidy (Manufacturer's Price) \$	Sub Per	Fully sidised	Brand or Generic Manufacturer
OPIRAMATE				
Tab 25 mg	11.07	60		Arrow-Topiramate Fopiramate Actavis
	26.04		🗸 1	Fopamax
Tab 50 mg		60		Arrow-Topiramate
	44.26		🗸 1	Горатах
Tab 100 mg	31.99	60		Arrow-Topiramate Topiramate Actavis
	75.25		🗸 1	Горатах
Tab 200 mg	55.19	60		Arrow-Topiramate Topiramate Actavis
	129.85		🗸 1	Горатах
Sprinkle cap 15 mg	20.84	60	۲ 🗸	Горатах
Sprinkle cap 25 mg	26.04	60	۲ 🗸	Topamax
IGABATRIN – Special Authority see SA2088 below – Retail p	bharmacy			
Tab 500 mg		100	√ 9	Sabril
Powder for oral soln 500 mg per sachet		60	√ 9	Sabril

#### SA2088 Special Authority for Subsidy

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

- 1 Any of the following:
  - 1.1 Patient has infantile spasms; or
  - 1.2 Both:
    - 1.2.1 Patient has epilepsy; and
    - 1.2.2 Either:
      - 1.2.2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
      - 1.2.2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; or
  - 1.3 Patient has tuberous sclerosis complex; and
- 2 Either:
  - 2.1 Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or
  - 2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields..

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

Both:

- 1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and
- 2 Either:
  - 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...

Antimigraine Preparations		
For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 118		
Acute Migraine Treatment		
RIZATRIPTAN Tab orodispersible 10 mg4.84	30	✓ <u>Rizamelt</u>

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

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

	Subsidy (Manufacturer's Prie \$	ce) Sub Per	Fully Brand or sidised Generic Manufacturer
JMATRIPTAN			
Tab 50 mg		90	✓ <u>Sumagran</u>
Tab 100 mg		90	<ul> <li>Sumagran</li> </ul>
Inj 12 mg per ml, 0.5 ml prefilled pen – Maximum of 10 inj p prescription		2 OP	<ul> <li>Clustran</li> </ul>
Prophylaxis of Migraine			
or Beta Adrenoceptor Blockers refer to CARDIOVASCULAR S	YSTEM, page 49		
ZOTIFEN Tab 500 mcg	23.21	100	<ul> <li>Sandomigran</li> </ul>
Antinausea and Vertigo Agents			
or Antispasmodics refer to ALIMENTARY TRACT, page 8			
PREPITANT – Special Authority see SA0987 below – Retail p Cap 2 × 80 mg and 1 × 125 mg		3 OP	Emend Tri-Pack
itial application from any relevant practitioner. Approvals val netogenic chemotherapy and/or anthracycline-based chemoth enewal from any relevant practitioner. Approvals valid for 12 r emotherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE	erapy for the treatn months where the p	nent of malig	nancy.
Tab 16 mg YCLIZINE HYDROCHLORIDE	3.70	100	✓ <u>Serc</u>
Tab 50 mg	0.66	10	<ul> <li>Nausicalm</li> </ul>
YCLIZINE LACTATE			
Inj 50 mg per ml, 1 ml ampoule – Up to 10 inj available on a	a		
PSO		10	<ul> <li>HameIn</li> </ul>
OMPERIDONE			
OMPERIDONE Tab 10 mg	3.80	100	✓ Domperidone Viatris
	3.80	100	•
Tab 10 mg		100 10	•
Tab 10 mg	93.00		Viatris

### ► SA1998 Special Authority for Subsidy

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

- 1 Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease where the patient cannot tolerate or does not adequately respond to oral anti-nausea agents; or
- 2 Control of clozapine-induced hypersalivation where trials of at least two other alternative treatments have proven ineffective.

Renewal from any relevant practitioner. Approvals valid for 1 year where the treatment remains appropriate and the patient is benefiting from treatment.

(Manufacturer's Price)         Subsidised Per         Generic Manufacturer           METOCLOPRAMIDE HYDROCHLORIDE         *         Metoclopramide Actavis 10           *         Inj 5 mg per ml. 2 ml ampoule – Up to 5 inj available on a PSO7.00         10         ✓         Baxter           ONDANSETRON         *         Tab 4 mg         -         Periset         Tab 4 mg         -         Periset           Tab 4 mg         -         Up to 10 tab available on a PSO		Subsidy		Fully	/ Brand or
METOCLOPRAMIDE HYDROCHLORIDE         Metoclopramide           * Tab 10 mg - Up to 30 tab available on a PSO		(Manufacturer's Price)			
* Tab 10 mg - Up to 30 tab available on a PSO       1.57       100       / Metoopramide Actavis 10         * Inj 5 mg per ml, 2 ml ampoule - Up to 5 inj available on a PSO       7.00       10       > Baxter         ONDANSETRON       ** Tab 4 mg       195       50       / Periset ODT         ** Tab 8 mg       195       50       / Periset ODT       * Periset ODT         ** Tab 8 mg       -0 to 10 tab available on a PSO       0.36       10       / Periset ODT         ** Tab 8 mg       -0 to 10 tab available on a PSO       0.90       10       / Periset ODT         PROCHLORPERAZINE       5.97       50       (30.00)       Prochlorperazine malatel (Brown & Burk)         ** Tab 5 mg - Up to 30 tab available on a PSO       .25.00       250       / Nausafix       * Burk)         ** Tab 5 mg - Up to 30 tab available on a PSO       .25.01       0       / Stemetil         Antipsychotics		\$	Per		Manufacturer
Actavis 10           Actavis 10           Actavis 10           Non-DANSETRON           ** Tab 4 mg	METOCLOPRAMIDE HYDROCHLORIDE				
**         Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO7.00         10         ✓ Baxter           ONDANSETRON         **         Tab disp 4 mg - Up to 10 tab available on a PSO	* Tab 10 mg – Up to 30 tab available on a PSO	1.57	100	✓	Metoclopramide
ONDANSETRON         Periset           ** Tab dr mg         1.95         50         ✓ Periset ODT           ** Tab & mg					Actavis 10
* Tab 4 mg       1.95       50       ✓ Periset ODT         * Tab 5 mg	* Inj 5 mg per ml, 2 ml ampoule - Up to 5 inj available on a F	SO7.00	10	✓	Baxter
* Tab 4 mg       1.95       50       ✓ Periset ODT         * Tab 5 mg	ONDANSETRON				
Tab disp <sup>2</sup> 4 mg - Up to 10 tab available on a PSO       0.56       10 <ul> <li>Periset ODT</li> <li>Tab dis g 8 mg - Up to 10 tab available on a PSO</li> <li>0.90</li> <li>10</li> <li>Periset ODT</li> </ul> PROCHLORPERAZINE       5.97       50 <ul> <li>Percohlorperazine maleate (Brown &amp; Burk)</li> <li>Tab dis g 8 mg - Up to 30 tab available on a PSO</li> <li>25.00</li> <li>25.00</li> <li>25.00</li> <li>X Nausafix</li> <li>Inj 12.5 mg per ml, 1 ml - Up to 5 inj available on a PSO</li> <li>25.81</li> <li>X Stemetil</li> </ul> Antipsychotics         Ceneral           AMISULPRIDE - Safety medicine; prescriber may determine dispensing frequency               Tab 100 mg             5.84 <li>Sulprix               Tab 200 mg             <ld>14.47</ld></li> <li>60</li> <li>Sulprix</li> ARIIPRAZOLE - Safety medicine; prescriber may determine dispensing frequency               Tab 10 mg <li>10.50</li> <li>X Aripiprazole Sandoz</li> <li>Tab 10 mg</li> <li>10.50</li> <li>X Aripiprazole Sandoz</li> <li>Tab 10 mg - Up 10 s0 tab available on a PSO</li> <li>15.62</li> <li>100</li> <li>X Aripiprazole Sandoz</li> <li>Tab 10 mg - Up 10 s0 tab available on a PSO</li> <li>15.62</li> <li>100</li> <li>X Aripiprazole Sandoz</li> <li>Tab 20</li>			50	1	Periset
Tab disp 8 mg - Up to 10 tab available on a PSO       0.90       10       ✓ Periset ODT         PROCHLORPERAZINE       .5.97       50         (30.00)       (30.00)       Prochlorperazine maleate (Brown & Burk)         * Tab 5 mg - Up to 30 tab available on a PSO       .25.00       250       ✓ Nausafix         * Tab 5 mg - Up to 30 tab available on a PSO       .25.81       10       ✓ Stemetil         Antipsychotics	8		10		
PROCHLOPERAZINE       ** Tab 3 mg buccal.       5.97       50         (30.00)       Prochlorperazine maleate (Brown & Burk)         ** Tab 5 mg – Up to 30 tab available on a PSO.       25.00       250       ✓ Nausafix         ** Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO.       25.81       10       ✓ Stemetil         AMISULPRIDE       – Safety medicine; prescriber may determine dispensing frequency       Tab 100 mg       5.84       30       ✓ Sulprix         Tab 200 mg	* Tab 8 mg	3.50	50	1	Periset
* Tab 3 mg buccal	Tab disp 8 mg - Up to 10 tab available on a PSO	0.90	10	1	Periset ODT
* Tab 3 mg buccal	PROCHI ORPERAZINE				
(30.00)         Prochlorperazine maleate (Brown & Burk)           ** Tab 5 mg - Up to 30 tab available on a PSO.         25.00         250         ✓ Nausafix           ** Inj 12.5 mg per ml, 1 ml - Up to 5 inj available on a PSO.         25.81         10         ✓ Sternetil           Antipsychotics         E         5.84         30         ✓ Sulprix           Tab 100 mg         5.84         30         ✓ Sulprix           Tab 200 mg         14.47         60         ✓ Sulprix           Tab 400 mg         5.86         30         ✓ Sulprix           Tab 200 mg         14.47         60         ✓ Sulprix           Tab 200 mg         10.50         30         ✓ Aripiprazole Sandoz           Tab 10 mg         10.50         30         ✓ Aripiprazole Sandoz           Tab 20 mg         10.50         30         ✓ Aripiprazole Sandoz           Tab 20 mg         0.50         30         ✓ Aripiprazole Sandoz           Tab 20 mg         0.50         30         ✓ Aripiprazole Sandoz           Tab 20 mg         0.50         30         ✓ Aripiprazole Sandoz           Tab 20 mg         -Up to 30 tab available on a PSO         5.62         100         ✓ Largactil           Tab 20 mgUp to 30 tab available on a PSO         <		5.97	50		
maleade (Brown & Burk)         * Tab 5 mg - Up to 30 tab available on a PSO.       25.0       250       ✓ Nausafix         * Inj 12.5 mg per ml, 1 ml - Up to 5 inj available on a PSO.       25.81       10       ✓ Stemetil         Antipsychotics       5.84       30       ✓ Sulprix       × Sulprix         Tab 100 mg       5.84       30       ✓ Sulprix       × Sulprix         Tab 400 mg       5.84       30       ✓ Sulprix       × Sulprix         Tab 400 mg       5.84       30       ✓ Sulprix       × Sulprix         ARIPIPRAZOLE - Safety medicine; prescriber may determine dispensing frequency       × Sulprix       × Sulprix         ARIPIPRAZOLE - Safety medicine; prescriber may determine dispensing frequency       × Aripiprazole Sandoz       × Aripiprazole Sandoz         Tab 5 mg       10.50       30       ✓ Aripiprazole Sandoz       × Aripiprazole Sandoz         Tab 10 mg       10.50       30       ✓ Aripiprazole Sandoz       × Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz       × Aripiprazole Sandoz         Tab 10 mg       Up to 30 tab available on a PSO       36.73       100       ✓ Largactil         Tab 25 mg       Up to 30 tab available on a PSO       36.73       100       ✓ Largactil					Prochlorperazine
* Tab 5 mg - Up to 30 tab available on a PSO       25.00       250       Y Nausafix         * Inj 12.5 mg per ml, 1 ml - Up to 5 inj available on a PSO       25.81       10       Y Nausafix         Antipsychotics         General         AMISULPRIDE - Safety medicine; prescriber may determine dispensing frequency Tab 100 mg       5.84       30       Y Sulprix         Tab 400 mg       5.84       30       Y Sulprix         Tab 400 mg       5.84       30       Y Sulprix         Tab 400 mg       5.66       60       Y Sulprix         ARIPIPRAZOLE - Safety medicine; prescriber may determine dispensing frequency         Tab 5 mg       10.50       30       Y Aripiprazole Sandoz         Tab 10 mg       10.50       30       Y Aripiprazole Sandoz         Tab 3 mg       10.50       30       Y Aripiprazole Sandoz         Tab 30 mg       10.50       30       Y Aripiprazole Sandoz         Tab 20 mg       10.50       30       Y Aripiprazole Sandoz         Tab 10 mg       Up to 30 tab available on a PSO       5.62       100       Y Largactil         Tab 20 mg - Up to 30 tab available on a PSO       36.73       100       Y Largactil         Tab 100 mg       Cl 2 The PSP - Super May		()			
* Tab 5 mg - Up to 30 tab available on a PSO					
★       Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO	* Tab 5 mg – Up to 30 tab available on a PSO	25.00	250	1	,
Antipsychotics         General         AMISULPRIDE - Safety medicine; prescriber may determine dispensing frequency Tab 100 mg       5.84       30       Sulprix         Tab 200 mg       14.47       60       Sulprix         Tab 400 mg       35.06       60       Sulprix         ARIPIPRAZOLE - Safety medicine; prescriber may determine dispensing frequency       10.50       30       A Aripiprazole Sandoz         Tab 5 mg       10.50       30       Aripiprazole Sandoz       10.50       30       A Aripiprazole Sandoz         Tab 200 mg       10.50       30       A Aripiprazole Sandoz       10.50       30       A Aripiprazole Sandoz         Tab 200 mg       10.50       30       A Aripiprazole Sandoz       10.50       30       A Aripiprazole Sandoz         Tab 20 mg       10.50       30       A Aripiprazole Sandoz       10.50       30       A Aripiprazole Sandoz         Tab 20 mg       10.50       30       A Aripiprazole Sandoz       10.50       30       A Aripiprazole Sandoz         Tab 20 mg       Up to 30 tab available on a PSO       16.52       100       Largactil       10.50         Tab 25 mg       Up to 5 inj available on a PSO       36.73       100       Largactil       11.337       100       Clozar	0 1				
General         AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency Tab 100 mg       5.84       30       < Sulprix	· · · · · · · · · · · · · · · · · · ·				
General         AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency Tab 100 mg       5.84       30       < Sulprix	Antipsychotics				
AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency Tab 100 mg					
Tab 100 mg       5.84       30       ✓ Sulprix         Tab 200 mg       14.47       60       ✓ Sulprix         Tab 400 mg	General				
Tab 100 mg       5.84       30       ✓ Sulprix         Tab 200 mg       14.47       60       ✓ Sulprix         Tab 400 mg					
Tab 200 mg					
Tab 400 mg35.0660✓ SulprixARIPIPRAZOLE - Safety medicine; prescriber may determine dispensing frequency Tab 5 mg10.5030✓ Aripiprazole SandozTab 10 mg10.5030✓ Aripiprazole SandozTab 10 mg10.5030✓ Aripiprazole SandozTab 20 mg10.5030✓ Aripiprazole SandozTab 30 mg10.5030✓ Aripiprazole SandozTab 30 mg10.5030✓ Aripiprazole SandozCHLORPROMAZINE HYDROCHLORIDE - Safety medicine; prescriber may determine dispensing frequency✓ LargactilTab 25 mg - Up to 30 tab available on a PSO15.62100✓ LargactilTab 100 mg - Up to 30 tab available on a PSO36.73100✓ LargactilInj 25 mg per Ml, 2 ml - Up to 5 inj available on a PSO30.7910✓ LargactilCLOZAPINE - Hospital pharmacy [HP4] Safety medicine; prescriber may determine dispensing frequency✓ ClozarilTab 50 mg17.33100✓ ClopineTab 50 mg17.33100✓ ClopineTab 100 mg17.3300✓ ClopineTab 100 mg17.3300✓ ClopineTab 100 mg34.65100✓ ClopineTab 100 mg34.6550✓ ClopineTab 100 mg34.65100✓ ClopineTab 100 mg34.65100✓ ClopineTab 100 mg34.65100✓ ClopineYab 200 mg34.6550✓ ClopineTab 200 mg34.6550✓ Clopine <t< td=""><td>5</td><td></td><td></td><td></td><td></td></t<>	5				
ARIPIPRAZOLE - Safety medicine; prescriber may determine dispensing frequency Tab 5 mg	5				
Tab 5 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 10 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 15 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 20 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 25 mg       -Up to 30 tab available on a PSO       15.62       100       ✓ Largactil         Tab 100 mg       -Up to 30 tab available on a PSO       36.73       100       ✓ Largactil         Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO       30.79       10       ✓ Largactil         CLOZAPINE – Hospital pharmacy [HP4]       Safety medicine; prescriber may determine dispensing frequency       ✓ Clozarii         Tab 25 mg       100       ✓ Clopine       ✓ Clozarii         Tab 50 mg       17.33       100       ✓ Clopine         Tab 50 mg       17.33       50	Tab 400 mg		60	/	<u>Sulprix</u>
Tab 10 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 15 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 20 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       0.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency       Tab 20 mg       ✓ Largactil         Tab 100 mg – Up to 30 tab available on a PSO       36.73       100       ✓ Largactil         Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO       30.79       10       ✓ Largactil         CLOZAPINE – Hospital pharmacy [HP4]       Safety medicine; prescriber may determine dispensing frequency       13.37       100       ✓ Clopine         Tab 20 mg       13.37       100       ✓ Clopine       ✓ Clozaril         Tab 50 mg       17.33       100       ✓ Clopine       ✓ Clozaril         Tab 100 mg       17.33       100       ✓ Clopine	ARIPIPRAZOLE - Safety medicine; prescriber may determine of	dispensing frequency			
Tab 15 mg10.5030✓ Aripiprazole SandozTab 20 mg10.5030✓ Aripiprazole SandozTab 30 mg10.5030✓ Aripiprazole SandozTab 30 mg10.5030✓ Aripiprazole SandozCHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency30✓ Aripiprazole SandozTab 25 mg – Up to 30 tab available on a PSO15.62100✓ LargactilTab 100 mg – Up to 30 tab available on a PSO36.73100✓ LargactilInj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO30.7910✓ LargactilCLOZAPINE – Hospital pharmacy [HP4]Safety medicine; prescriber may determine dispensing frequency✓ ClozarilTab 50 mg6.6950✓ Clopine✓ ClozarilTab 50 mg17.33100✓ Clopine✓ ClozarilTab 100 mg17.3350✓ Clopine✓ ClozarilTab 200 mg34.6550✓ ClopineChopine69.30100✓ Clopine	Tab 5 mg	10.50	30	1	Aripiprazole Sandoz
Tab 20 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency       15.62       100       ✓ Largactil         Tab 100 mg – Up to 30 tab available on a PSO       15.62       100       ✓ Largactil         Tab 100 mg – Up to 30 tab available on a PSO       36.73       100       ✓ Largactil         Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO       30.79       10       ✓ Largactil         CLOZAPINE – Hospital pharmacy [HP4]       Safety medicine; prescriber may determine dispensing frequency       ✓ Clopine       ✓ Clopine         Tab 50 mg       13.37       100       ✓ Clopine       ✓ Clopine         Tab 50 mg       8.67       50       ✓ Clopine       ✓ Clopine         Tab 100 mg       17.33       100       ✓ Clopine       ✓ Clopine         Tab 100 mg       17.33       50       ✓ Clopine       ✓ Clopine         Tab 200 mg       34.65       50       ✓ Clopine       ✓ Cloparil         Tab 200 mg       34.65       50       ✓ Clopine       ✓ Cloparil         69.30       100       ✓ Clopine       ✓ Clopine       ✓ Clopine <td>Tab 10 mg</td> <td>10.50</td> <td>30</td> <td></td> <td></td>	Tab 10 mg	10.50	30		
Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency       15.62       100       ✓ Largactil         Tab 25 mg – Up to 30 tab available on a PSO       15.62       100       ✓ Largactil         Tab 100 mg – Up to 30 tab available on a PSO       36.73       100       ✓ Largactil         Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO       30.79       10       ✓ Largactil         CLOZAPINE – Hospital pharmacy [HP4]       Safety medicine; prescriber may determine dispensing frequency       7       ✓ Clopine         Tab 25 mg       6.69       50       ✓ Clopine       ✓ Cloparil         13.37       100       ✓ Clopine       ✓ Cloparil         Tab 50 mg       8.67       50       ✓ Clopine         Tab 100 mg       17.33       100       ✓ Clopine         Tab 100 mg       17.33       50       ✓ Clopine         Tab 100 mg       17.33       50       ✓ Clopine         Tab 200 mg       34.65       50       ✓ Cloparil         Tab 200 mg       34.65       50       ✓ Cloparil	Tab 15 mg	10.50	30	✓	Aripiprazole Sandoz
CHLORPROMAZINE HYDROCHLORIDE - Safety medicine; prescriber may determine dispensing frequency Tab 25 mg - Up to 30 tab available on a PSO	Tab 20 mg	10.50	30		
Tab 25 mg – Up to 30 tab available on a PSO       15.62       100       ✓ Largactil         Tab 100 mg – Up to 30 tab available on a PSO       36.73       100       ✓ Largactil         Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO       30.79       10       ✓ Largactil         CLOZAPINE – Hospital pharmacy [HP4]       Safety medicine; prescriber may determine dispensing frequency       6.69       50       ✓ Clopine         Tab 25 mg       13.37       100       ✓ Clopine       ✓ Cloparel         Tab 50 mg       8.67       50       ✓ Clopine         Tab 50 mg       17.33       100       ✓ Clopine         Tab 100 mg       17.33       50       ✓ Clopine         Tab 200 mg       34.65       50       ✓ Clopine         Tab 200 mg       34.65       50       ✓ Clopine         69.30       100       ✓ Clopine       ✓ Cloparel	Tab 30 mg	10.50	30	~	Aripiprazole Sandoz
Tab 100 mg – Úp to 30 tab available on a PSO	CHLORPROMAZINE HYDROCHLORIDE - Safety medicine; p	rescriber may determi	ne dis	spensing fi	requency
Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO	Tab 25 mg – Up to 30 tab available on a PSO		100	<ul> <li>✓</li> </ul>	Largactil
CLOZAPINE - Hospital pharmacy [HP4] Safety medicine; prescriber may determine dispensing frequency Tab 25 mg	Tab 100 mg - Up to 30 tab available on a PSO		100	✓	Largactil
Safety medicine; prescriber may determine dispensing frequency Tab 25 mg	Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO		10	1	Largactil
Safety medicine; prescriber may determine dispensing frequency Tab 25 mg	CLOZAPINE – Hospital pharmacy [HP4]				
Tab 25 mg       6.69       50       ✓ Clopine         13.37       100       ✓ Clopine         13.37       100       ✓ Clopine         ✓ Clozaril       ✓ Clozaril         Tab 50 mg       8.67       50         Tab 50 mg       17.33       100       ✓ Clopine         Tab 100 mg       17.33       50       ✓ Clopine         ✓ Clozaril       ✓ Clopine       ✓ Clopine         34.65       100       ✓ Clopine         ✓ Clozaril       ✓ Clozaril         Tab 200 mg       34.65       50       ✓ Clopine         69.30       100       ✓ Clopine		Jency			
13.37       100       ✓ Clopine         ✓ Clozaril       ✓ Clozaril         Tab 50 mg       8.67       50       ✓ Clopine         17.33       100       ✓ Clopine         Tab 100 mg       17.33       50       ✓ Clopine         34.65       100       ✓ Clopine       ✓ Clozaril         34.65       100       ✓ Clopine       ✓ Clozaril         Tab 200 mg       34.65       50       ✓ Clopine         69.30       100       ✓ Clopine       ✓ Clopine		•	50	1	Clopine
✓ Clozaril Tab 50 mg8.67 50 ✓ Clopine 17.33 100 ✓ Clopine 17.33 50 ✓ Clopine ✓ Clozaril 34.65 100 ✓ Clopine ✓ Clozaril Tab 200 mg	,			1	Clozaril
Tab 50 mg       8.67       50       ✓ Clopine         17.33       100       ✓ Clopine         Tab 100 mg       17.33       50       ✓ Clopine         34.65       100       ✓ Clopine       ✓ Clozaril         34.65       100       ✓ Clopine       ✓ Clozaril         Tab 200 mg       34.65       50       ✓ Clopine         69.30       100       ✓ Clopine       ✓ Clopine		13.37	100	✓	Clopine
17.33       100       ✓ Clopine         Tab 100 mg       17.33       50       ✓ Clopine         34.65       100       ✓ Clopine       ✓ Clopine         Tab 200 mg       34.65       50       ✓ Clopine         69.30       100       ✓ Clopine       ✓ Clopine				✓	Clozaril
Tab 100 mg       17.33       50       ✓ Clopine         34.65       100       ✓ Clopine         Tab 200 mg       34.65       50       ✓ Clopine         69.30       100       ✓ Clopine	Tab 50 mg	8.67	50		•
✓ Clozaril 34.65 100 ✓ Clopine ✓ Clozaril Tab 200 mg					•
34.65       100       ✓ Clopine         ✓ Clozaril       ✓ Clozaril         Tab 200 mg	Tab 100 mg		50		•
✓ Clozaril Tab 200 mg					
Tab 200 mg         34.65         50         ✓ Clopine           69.30         100         ✓ Clopine		34.65	100		•
69.30 100 <b>✓ Clopine</b>					
	Tab 200 mg				
Suspension 50 mg per ml 173.30 100 ml 🖌 Versacloz					•
	Suspension 50 mg per ml		100 n	nl 🗸	Versacloz

▲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 \$	e) Per	Subsidised G	Brand or Generic Manufacturer
ALOPERIDOL – Safety medicine; prescriber may determine dis	pensing frequency			
Tab 500 mcg – Up to 30 tab available on a PSO		100	🗸 Sere	enace
Tab 1.5 mg - Up to 30 tab available on a PSO		100	✓ Sere	enace
Tab 5 mg – Up to 30 tab available on a PSO		50	🗸 Sere	enace
	29.72	100	✓ Sere	enace
Oral liq 2 mg per ml – Up to 200 ml available on a PSO		100 m	l 🖌 Sere	enace
Inj 5 mg per ml, 1 ml ampoule - Up to 5 inj available on a PS	O21.55	10	<ul> <li>Sere</li> </ul>	enace
EVOMEPROMAZINE - Safety medicine; prescriber may determ	ine dispensing frea	uencv		
Tab 25 mg (33.8 mg as a maleate)		100	🗸 Noz	inan (Swiss)
Tab 25 mg as a maleate		100	✓ Noz	
Tab 100 mg (135 mg as a maleate)		100	🗸 Noz	inan (Swiss)
Tab 100 mg as a maleate		100	🗸 Noz	
EVOMEPROMAZINE HYDROCHLORIDE – Safety medicine; pi		mino d	lisponsina frogu	IANOV
Inj 25 mg per ml, 1 ml ampoule	•	10		khardt
				- Kilalut
ITHIUM CARBONATE – Safety medicine; prescriber may detern				.1.1
Tab long-acting 400 mg		100	✓ <u>Pria</u>	
Cap 250 mg		100	🗸 Dou	igias
DLANZAPINE – Safety medicine; prescriber may determine disp				
Tab 2.5 mg		30	✓ Zypi	
Tab 5 mg		30	<ul> <li>Zypi</li> </ul>	
Tab orodispersible 5 mg		28		ine ODT
Tab 10 mg		30	✓ Zyp	
Tab orodispersible 10 mg	2.89	28	✓ Zypi	ine ODT
ERICYAZINE - Safety medicine; prescriber may determine disp	ensing frequency			
Tab 2.5 mg		100	🖌 Neu	lactil
Tab 10 mg		100	🗸 Neu	lactil
UETIAPINE – Safety medicine; prescriber may determine dispe	ensing frequency			
Tab 25 mg	0 1 7	30	🗸 Que	tianine
1 do 20 mg		00		atris S29
	0.06	00		
	2.36 13.11	90 500	✓ <u>Que</u>	ntaper Itiapine
	13.11	500		•
				atris S29
Tab 100 mg		90	✓ <u>Que</u>	
Tab 200 mg		90	✓ <u>Que</u>	
Tab 300 mg		90	✓ Que	tapel

()	Subsidy Manufacturer's Price)	S	Fully	
Υ.	\$	Per	1	
RISPERIDONE - Safety medicine; prescriber may determine dispe	ensing frequency			
Tab 0.5 mg	• • •	20	~	Risperdal
ő	2.17	60	1	Risperidone (Teva)
	4.01			Risperidone
				Sandoz S29
Tab 1 mg	2.44	60	1	Risperdal
·				Risperidone (Teva)
	3.68			Risperidone
				Sandoz S29
Tab 2 mg	2.72	60	1	Risperdal
· ~~				Risperidone (Teva)
	5.38			Risperidone
				Sandoz S29
Tab 3 mg	4 50	60	1	Risperdal
		00		Risperidone (Teva)
	8.57			Risperidone
				Sandoz S29
Tab 4 mg	6 25	60	1	Risperdal
1 au + mg	0.20	00		Risperidone (Teva)
Oral liq 1 mg per ml	10.29	30 ml		Risperon
Risperdal Tab 0.5 mg to be delisted 1 September 2025)				<u></u>
Risperidone Sandoz <sup>(22)</sup> Tab 0.5 mg to be delisted 1 September	2025)			
Risperdal Tab 1 mg to be delisted 1 September 2025)	2023)			
Risperidone Sandoz <sup>(229)</sup> Tab 1 mg to be delisted 1 September 20	125)			
Risperdal Tab 2 mg to be delisted 1 September 2025)	)23)			
Risperidone Sandoz <sup>(629)</sup> Tab 2 mg to be delisted 1 September 20	125)			
Risperdal Tab 3 mg to be delisted 1 September 2025)	020)			
Risperidone Sandoz <sup>(229)</sup> Tab 3 mg to be delisted 1 September 20	125)			
	,			
(IPRASIDONE – Safety medicine; prescriber may determine dispe		~~		<b>7</b>
Cap 20 mg		60 60		Zusdone Zusdone
Cap 40 mg		60 60		Zusdone
Cap 60 mg		60 60		Zusdone
		•••		
CUCLOPENTHIXOL HYDROCHLORIDE – Safety medicine; presc	•	•	-	· ·
Tab 10 mg	31.45	100	<b>v</b>	Clopixol
Depot Injections				
RIPIPRAZOLE – Special Authority see SA2395 below – Retail ph	armacy			
Safety medicine; prescriber may determine dispensing frequent	су			
Inj 300 mg vial	273.56	1	1	Abilify Maintena
Inj 400 mg vial	341.96	1	✓	Abilify Maintena
SA2395 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 Either:

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

continued...

- 1.1 The patient has had an initial Special Authority approval for risperidone depot injection, paliperidone depot injection or olanzapine depot injection; or
- 1.2 All of the following:
  - 1.2.1 The patient has schizophrenia or other psychotic disorder; and
  - 1.2.2 The patient has received treatment with oral atypical antipsychotic agents but has been unable to adhere; and
  - 1.2.3 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 last 12 months; or
- 2 Patient has been unable to access olanzapine depot injection due to supply issues with olanzapine depot injection, or otherwise would have been started on olanzapine depot injection but has been unable to due to supply issues with olanzapine depot injection.

Notes: The Olanzapine depot injection Special Authority criteria that apply to criterion 2 in this Aripiprazole Special Authority application are as follows:

- The patient has had an initial Special Authority approval for paliperidone depot injection or risperidone depot injection; or
- All of the following:
  - The patient has schizophrenia; and
  - The patient has not been able to adhere with treatment using oral atypical antipsychotic agents; and
  - 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.

FLUPENTHIXOL DECANOATE - Safety medicine; prescriber may determine dispe	nsing freq	uency
Inj 20 mg per ml, 1 ml – Up to 5 inj available on a PSO	5	<ul> <li>Fluanxol</li> </ul>
Inj 20 mg per ml, 2 ml – Up to 5 inj available on a PSO20.90	5	<ul> <li>Fluanxol</li> </ul>
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	5	<ul> <li>Fluanxol</li> </ul>
HALOPERIDOL DECANOATE - Safety medicine; prescriber may determine dispen	ising frequ	ency
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	5	<ul> <li>Haldol</li> </ul>
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO55.90	5	<ul> <li>Haldol Concentrate</li> </ul>
		<ul> <li>Haldol</li> </ul>
		Decanoas S29
OLANZAPINE – Special Authority see SA2313 below – Retail pharmacy		
a) Safety medicine; prescriber may determine dispensing frequency		
<li>b) Note – no new patients to be initiated on olanzapine.</li>		
Inj 210 mg vial252.00	1	<ul> <li>Zyprexa Relprevv</li> </ul>
Inj 300 mg vial414.00	1	<ul> <li>Zyprexa Relprevv</li> </ul>
Inj 405 mg vial504.00	1	<ul> <li>Zyprexa Relprevv</li> </ul>

#### SA2313 Special Authority for Subsidy

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.

PALIPERIDONE - Special Authority see SA2396 on the next page - Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency

Inj 25 mg syringe	 1	🗸 Invega Sustenna
Inj 50 mg syringe	1	Invega Sustenna
Inj 75 mg syringe	1	Invega Sustenna
Inj 100 mg syringe	 1	Invega Sustenna
Inj 150 mg syringe	 1	🗸 Invega Sustenna

Out-it.		E. Iler	Durand an
Subsidy		Fully	Brand or
(Manufacturer's Price)	5	Subsidised	Generic
\$	Per	1	Manufacturer

#### ⇒SA2396 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 been unable to adhere to 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.

PALIPERIDONE PALMITATE - Special Auth	ority see <mark>SA2167 below</mark> – Retail pharma	асу	
Inj 175 mg syringe		1	🖌 Invega Trinza
Inj 263 mg syringe	1,072.26	1	🗸 Invega Trinza
Inj 350 mg syringe	1,305.36	1	🗸 Invega Trinza
Inj 525 mg syringe		1	🗸 Invega Trinza
			-

#### ➡SA2167 Special Authority for Subsidy

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

- 1 The patient has schizophrenia; and
- 2 The patient has had an initial Special Authority approval for paliperidone once-monthly depot injection.

**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.

RISPERIDONE - Special Authority see SA2397 below - Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency

Inj 25 mg vial	1	<ul> <li>Risperdal Consta</li> </ul>
Inj 37.5 mg vial	1	<ul> <li>Risperdal Consta</li> </ul>
Inj 50 mg vial217.56	1	<ul> <li>Risperdal Consta</li> </ul>

#### ⇒SA2397 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 not been able to adhere 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.

#### ZUCLOPENTHIXOL DECANOATE - Safety medicine; prescriber may determine dispensing frequency

Inj 200 mg per ml, 1 ml	- Up to 5 inj available on a PSO		<ul> <li>Clopixol</li> </ul>
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	Subsidy (Manufacturer's Price) \$	Subs Per	Fully idised	Brand or Generic Manufacturer
Anxiolytics				
BUSPIRONE HYDROCHLORIDE				
* Tab 5 mg		100	✓ B	Suspirone Viatris
* Tab 10 mg		100	✓ B	Suspirone Viatris
CLONAZEPAM - Safety medicine; prescriber may determine dis	spensing frequency			
Tab 500 mcg		100	✓ P	axam
Tab 2 mg	10.78	100	✓ P	axam
DIAZEPAM - Safety medicine; prescriber may determine dispen	sing frequency			
Tab 2 mg		500	🗸 A	rrow-Diazepam
Tab 5 mg	115.00	500	🗸 🗸	rrow-Diazepam
LORAZEPAM - Safety medicine; prescriber may determine disp	ensing frequency			
Tab 1 mg		250	🗸 🖌	tivan
Tab 2.5 mg		100	✓ <u>A</u>	tivan

### **Multiple Sclerosis Treatments**

#### ⇒SA2274 Special Authority for Subsidy

Initial application — (Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab and teriflunomide) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been confirmed by a neurologist; and
  - 1.2 Patient has an EDSS score between 0 6.0; and
  - 1.3 Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months; and
  - 1.4 All of the following:
    - 1.4.1 Each significant attack must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic); and
    - 1.4.2 Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
    - 1.4.3 Each significant attack has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant); and
    - 1.4.4 Each significant attack can be distinguished from the effects of general fatigue; and is not associated with a fever (T>  $37.5^{\circ}$ C); and
    - 1.4.5 Either:
      - 1.4.5.1 Each significant attack is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or
      - 1.4.5.2 Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and
  - 1.5 Evidence of new inflammatory activity on an MRI scan within the past 24 months; and
  - 1.6 Any of the following:
    - 1.6.1 A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion; or

	Subsidy (Manufacturer's Price) \$	Subsi Per	Fully idised	Brand or Generic Manufacturer
continued				
continued 1.6.2 A sign of that new inflammatory activity is a 1.6.3 A sign of that new inflammatory activity is a 1.6.4 A sign of that new inflammatory activity is a features of a recent attack that occurred with 1.6.5 A sign of that new inflammatory activity is ne 2 Patient has an active approval for ocrelizumab and does ne Note: Treatment on two or more funded multiple sclerosis treatmer <b>Renewal — (Multiple Sclerosis - dimethyl fumarate, fingolimo beta-1-beta, natalizumab and teriflunomide)</b> from any relevant had an EDSS score of 0 to 6.0 (inclusive) with or without the use of the patient has walked 100 metres or more with or without aids in Note: Treatment on two or more funded multiple sclerosis treatmer DIMETHYL FUMARATE – Special Authority see SA2274 on the p	In with associated loc prominent T2 lesion to hin the last 2 years; o ew T2 lesions compar- ot have primary progre- ents simultaneously is <b>d, glatiramer acetat</b> practitioner. Approv of unilateral or bilatera- the last six months). ents simultaneously is	cal swelling that clearly red with a ressive MS s not perm <b>e, interfer</b> als valid fo al aids at a s not perm	g; or / is resp previou S. hitted. or 12 m any time hitted.	us MRI scan; or <b>a-1-alpha, interferon</b> onths where patient has
a) Wastage claimable b) Note: Treatment on two or more funded multiple sclerosis Cap 120 mg Cap 240 mg		eously is r 14 56	🖌 T	nitted. ecfidera ecfidera
FINGOLIMOD - Special Authority see SA2274 on the previous pa	age – Retail pharmac	cy .		
<ul> <li>a) Wastage claimable</li> <li>b) Note: Treatment on two or more funded multiple sclerosis</li> <li>Cap 0.5 mg</li> </ul>	treatments simultan	eously is r 28	🗸 G	nitted. <b>ilenya</b>
GLATIRAMER ACETATE – Special Authority see SA2274 on the Note: Treatment on two or more funded multiple sclerosis tre Inj 40 mg prefilled syringe	atments simultaneou	ail pharma Isly is not j 12	permitte	ed. <b>opaxone</b>
INTERFERON BETA-1-ALPHA – Special Authority see SA2274 o Note: Treatment on two or more funded multiple sclerosis tree Inj 6 million iu prefilled syringe Injection 6 million iu per 0.5 ml pen injector	atments simultaneou 1,170.00 1,170.00	isly is not j 4 4	permitte	
INTERFERON BETA-1-BETA – Special Authority see SA2274 or Note: Treatment on two or more funded multiple sclerosis tre Inj 8 million iu per 1 ml	atments simultaneou		permitte	
NATALIZUMAB – Special Authority see SA2274 on the previous Note: Treatment on two or more funded multiple sclerosis tre Inj 20 mg per ml, 15 ml vial	atments simultaneou			ed. <b>ysabri</b>
<ul> <li>TERIFLUNOMIDE – Special Authority see SA2274 on the previou</li> <li>a) Wastage claimable</li> <li>b) Note: Treatment on two or more funded multiple sclerosis</li> <li>Tab 14 mg</li> </ul>	treatments simultan			nitted. eriflunomide Sandoz
Multiple Sclerosis Treatments - Other				

#### 

▲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		Fully	Brand or
(Manufacturer's Price)		Subsidised	Generic
\$	Per	<u> </u>	Manufacturer

### ⇒SA2273 Special Authority for Subsidy

**Initial application** — (Multiple Sclerosis - ocrelizumab) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been confirmed by a neurologist; and
  - 1.2 Patient has an EDSS score between 0 6.0; and
  - 1.3 Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months; and
  - 1.4 All of the following:
    - 1.4.1 Each significant attack must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic); and
    - 1.4.2 Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
    - 1.4.3 Each significant attack has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant); and
    - 1.4.4 Each significant attack can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C); and
    - 1.4.5 Either:
      - 1.4.5.1 Each significant attack is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or
      - 1.4.5.2 Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and
  - 1.5 Evidence of new inflammatory activity on an MRI scan within the past 24 months; and
  - 1.6 Any of the following:
    - 1.6.1 A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion; or
    - 1.6.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or
    - 1.6.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or
    - 1.6.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack that occurred within the last 2 years; or
    - 1.6.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan; or
- 2 Patient has an active Special Authority approval for either dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab or teriflunomide.

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

Renewal — (Multiple Sclerosis - ocrelizumab) from any relevant practitioner. 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 (ie the patient has walked 100 metres or more with or without aids in the last six months).

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

Initial application — (Primary Progressive Multiple Sclerosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Diagnosis of primary progressive multiple sclerosis (PPMS) meets the 2017 McDonald criteria and has been confirmed by a neurologist; and
- 2 Patient has an EDSS 2.0 (score equal to or greater than 2 on pyramidal functions) to EDSS 6.5; and

Viaisom

 Subsidy (Manufacturer's Price)	Su	Fully bsidised	Brand or Generic
(Manulacialei s i lice) \$	Per		Manufacturer

continued...

3 Patient has no history of relapsing remitting multiple sclerosis.

Renewal — (Primary Progressive Multiple Sclerosis) from any relevant practitioner. Approvals valid for 12 months where patient has had an EDSS score of less than or equal to 6.5 at any time in the last six months (ie patient has walked 20 metres with bilateral assistance/aids, without rest in the last six months).

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### Sedatives and Hypnotics

MELATONIN - Special Authority see SA1666 below - Retail pharmacy

➡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	
Inj 1 mg per ml, 5 ml ampoule 7.80 10	idazolam-Baxter
Inj 1 mg per ml, 5 ml plastic ampoule – Up to 10 inj available	
on a PSO	izer
On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only	у.
Inj 5 mg per ml, 1 ml plastic ampoule – Up to 10 inj available	
on a PSO	idazolam-Pfizer
On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only	у.
Inj 5 mg per ml, 3 ml ampoule4.75 5 🖌 Mi	idazolam-Baxter
Inj 5 mg per ml, 3 ml plastic ampoule – Up to 5 inj available on	
a PSO	izer
On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only	у.
PHENOBARBITONE SODIUM - Special Authority see SA1386 on the next page - Retail pharmacy	
Inj 200 mg per ml, 1 ml ampoule 113.37 10 🗸 Ma	ax Health S29

Subsidy (Manufacturer's Pric \$	e) Per	Fully Subsidised	Brand or Generic Manufacturer
SA1386 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid without further rel the following criteria: Both:	iewal u	inless notifi	ed for applications meeting
<ol> <li>For the treatment of terminal agitation that is unresponsive to other agents; a</li> <li>The applicant is part of a multidisciplinary team working in palliative care.</li> </ol>	nd		
TEMAZEPAM – Safety medicine; prescriber may determine dispensing frequency Tab 10 mg1.40	25	1	Normison
ZOPICLONE – Safety medicine; prescriber may determine dispensing frequency Tab 7.5 mg21.85	500	1	Zopiclone Actavis
Spinal Muscular Atrophy			
NUSINERSEN - PCT only - Special Authority see SA2174 below			
Inj 12 mg per 5 ml vial	1	1	Spinraza
Initial application — (spinal muscular atrophy (SMA)) from any relevant practitic applications meeting the following criteria: All of the following: 1 Patient has genetic documentation of homozygous SMN1 gene deletion, hom			
heterozygous mutation; and 2 Patient is 18 years of age or under; and	iozygo		
<ul> <li>3 Either:</li> <li>3.1 Patient has experienced the defined signs and symptoms of SMA type</li> </ul>		r III.a prior t	a three wears of ago; or
3.1 Patient has experienced the defined signs and symptoms of SMA type 3.2 Both:	; 1, 11 0	ι πα μποι τ	o lillee years of age, of
<ul><li>3.2.1 Patient is pre-symptomatic; and</li><li>3.2.2 Patient has three or less copies of SMN2.</li></ul>			
Renewal — (spinal muscular atrophy (SMA)) from any relevant practitioner. App meeting the following criteria: All of the following:	rovals	valid for 12	months for applications
<ol> <li>There has been demonstrated maintenance of motor milestone function since</li> <li>Patient does not require invasive permanent ventilation (at least 16 hours per reversible cause while being treated with nusinersen; and</li> <li>Nusinersen not to be administered in combination other SMA disease modify</li> </ol>	day) i	n the abser	nce of a potentially
RISDIPLAM – [Xpharm] – Special Authority see SA2203 below Note: the supply of risdiplam is via Pharmac's approved direct distribution supp Pharmac's website https://pharmac.govt.nz/risdiplam	y. Fu	ther details	can be found on
Powder for oral soln 750 mcg per ml, 60 mg per bottle14,100.00	80 ml (	OP 🗸	Evrysdi
SA2203 Special Authority for Subsidy Initial application — (spinal muscular atrophy (SMA)) from any relevant practitic applications meeting the following criteria: All of the following:	ner. A	pprovals va	alid for 12 months for
<ol> <li>Patient has genetic documentation of homozygous SMN1 gene deletion, hon heterozygous mutation; and</li> <li>Patient is 18 years of age or under; and</li> <li>Either:</li> </ol>	iozygo	us SMN1 p	oint mutation, or compound

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

- 3.1 Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age; or 3.2 Both:
  - 3.2.1 Patient is pre-symptomatic: and
  - 3.2.2 Patient has three or less copies of SMN2.

Renewal — (spinal muscular atrophy (SMA)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 There has been demonstrated maintenance of motor milestone function since treatment initiation; and
- 2 Patient does not require invasive permanent ventilation (at least 16 hours per day) in the absence of a potentially reversible cause while being treated with risdiplam; and
- 3 Risdiplam not to be administered in combination other SMA disease modifying treatments or gene therapy.

## **Stimulants/ADHD Treatments**

### ATOMOXETINE

Cap 10 mg		28	APO-Atomoxetine
Cap 18 mg		28	✓ APO-Atomoxetine
Cap 25 mg		28	✓ APO-Atomoxetine
Cap 40 mg		28	✓ APO-Atomoxetine
Cap 60 mg		28	✓ APO-Atomoxetine
Cap 80 mg		28	✓ APO-Atomoxetine
Cap 100 mg	65.71	28	✓ APO-Atomoxetine
DEXAMFETAMINE SULFATE - Special Authority see SA241	0 below – Retail pha	irmacy	
a) Only on a controlled drug form	· · · · · · · · · · · · · · · · · · ·	,	
b) Safety medicine; prescriber may determine dispensing	frequency		
Tab 5 mg		100	<ul> <li>Noumed</li> <li>Dexamfetamine</li> </ul>

### ⇒SA2410 Special Authority for Subsidy

Initial application — (ADHD in patients aged 5 years 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 without further renewal unless notified for applications meeting the following criteria: All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) in patients aged 5 years or over; and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either:
  - 3.1 Applicant is a paediatrician or psychiatrist; or
  - 3.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

Initial application — (ADHD in patients aged under 5 years) only from a paediatrician or psychiatrist. Approvals valid without further renewal unless notified for applications meeting the following criteria: Both:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) in 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 without further renewal unless notified where the patient suffers from narcolepsy.

	Subsidy (Manufacturer's Price) \$	Su Per	Fully Ibsidised	Brand or Generic Manufacturer
LISDEXAMFETAMINE DIMESILATE – Special Authority see SA2	2415 below – Retail p	harmad	сy	
<ul> <li>a) Only on a controlled drug form</li> </ul>				
b) Safety medicine; prescriber may determine dispensing fre	quency			
Cap 30 mg - No more than 1 cap per day		30	🗸 V	yvanse
Cap 50 mg	60.00	30	🗸 V	yvanse

### ► SA2415 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 without further renewal unless notified for applications meeting the following criteria: Fither:

- 1 Patient is currently on treatment with lisdexamfetamine dimesilate and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 ADHD (Attention Deficit and Hyperactivity Disorder); and

- 2.2 Diagnosed according to DSM-V or ICD 11 criteria; and
- 2.3 Either:
  - 2.3.1 Applicant is a paediatrician or psychiatrist; or
  - 2.3.2 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

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Vvvanse

- 2.4 Any of the following:
  - 2.4.1 Patient is taking a currently subsidised formulation of atomoxetine or methylphenidate hydrochloride (extended-release) and has not received sufficient benefit or has experienced intolerable side effects; or
  - 2.4.2 Patient is taking a currently subsidised formulation of dexamfetamine sulfate (immediate-release) which has not been effective due to significant administration and/or treatment adherence difficulties; or
  - 2.4.3 There is significant concern regarding the risk of diversion or abuse of immediate release dexamfetamine sulfate; or
  - 2.4.4 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 treatment adherence difficulties; or
  - 2.4.5 There is significant concern regarding the risk of diversion or abuse of immediate release methylphenidate hydrochloride; or
  - 2.4.6 Both:
    - 2.4.6.1 Patient would have been prescribed a subsidised formulation of methylphenidate hydrochloride (extended-release) but has been unable to access due to supply issues with methylphenidate hydrochloride (extended-release); and
    - 2.4.6.2 Other alternative stimulant presentations (methylphenidate or dexamfetamine) are not appropriate; and
- 2.5 Lisdexamfetamine dimesilate is not to be used in combination with another funded methylphenidate presentation.

## NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
METHYLPHENIDATE HYDROCHLORIDE - Special Authority see	e SA2411 below – F	Retail p	oharmacy	
<ul> <li>a) Only on a controlled drug form</li> </ul>				
b) Safety medicine; prescriber may determine dispensing free	quency			
Tab immediate-release 5 mg		30	✓	Rubifen
Tab immediate-release 10 mg		30	1	Rubifen
	4.00		1	Ritalin
Tab extended-release 18 mg	7.75	30	~	Methylphenidate ER - Teva
Tab immediate-release 20 mg	7.85	30	1	Rubifen
Tab sustained-release 20 mg	10.95	30	1	Rubifen SR
Tab extended-release 27 mg	11.45	30	1	Methylphenidate ER - Teva
Tab extended-release 36 mg	15.50	30	1	Methylphenidate ER - Teva
Tab extended-release 54 mg	22.25	30	1	Methylphenidate ER - Teva

## ⇒SA2411 Special Authority for Subsidy

**Initial application** — (ADHD in patients aged 5 years 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 without further renewal unless notified for applications meeting the following criteria: All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) in patients aged 5 years or over; and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either:
  - 3.1 Applicant is a paediatrician or psychiatrist; or
  - 3.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

Initial application — (ADHD in patients aged under 5 years) only from a paediatrician or psychiatrist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

- Both:
  - 1 ADHD (Attention Deficit and Hyperactivity Disorder) in 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 without further renewal unless notified where the patient suffers from narcolepsy.

Note: \*narcolepsy is not a registered indication for Methylphenidate ER - Teva.

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE – Special Authority see SA2450 on the next page – Retail pharmacy

a) Only on a controlled drug form

<li>b) Safety medicine; prescriber may determine dispensing fre</li>	quency		
Tab extended-release 18 mg		30	<ul> <li>Concerta</li> </ul>
Tab extended-release 27 mg	65.44	30	<ul> <li>Concerta</li> </ul>
Tab extended-release 36 mg	71.93	30	<ul> <li>Concerta</li> </ul>
Tab extended-release 54 mg		30	<ul> <li>Concerta</li> </ul>
Cap modified-release 10 mg	19.41	30	<ul> <li>Ritalin LA</li> </ul>
Cap modified-release 20 mg	27.72	30	<ul> <li>Ritalin LA</li> </ul>
Cap modified-release 30 mg	34.39	30	<ul> <li>Ritalin LA</li> </ul>
Cap modified-release 40 mg		30	<ul> <li>Ritalin LA</li> </ul>

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

### ⇒SA2450 Special Authority for Subsidy

Initial application — (ADHD) 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 without further renewal unless notified for applications meeting the following criteria: Either:

- 1 All of the following:
  - 1.1 ADHD (Attention Deficit and Hyperactivity Disorder); and
  - 1.2 Diagnosed according to DSM-IV or ICD 10 criteria; and
  - 1.3 Either:
    - 1.3.1 Applicant is a paediatrician or psychiatrist; or
    - 1.3.2 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
  - 1.4 Either:
    - 1.4.1 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 difficulties with adherence; or
    - 1.4.2 There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride; or
- 2 Both:
  - 2.1 Patient meets the Special Authority criteria for SA2411 methylphenidate hydrochloride; and
  - 2.2 Patient is unable to access other methylphenidate hydrochloride presentations under Special Authority criteria SA2411 due to an out of stock (see note).

Note: Criterion 2 is to permit short-term funding to cover an out-of-stock on tab extended-release Methylphenidate ER – Teva and tab sustained-release 20 mg Rubifen SR subsidised under

SA2411 (https://schedule.pharmac.govt.nz/2025/02/01/SA2411.pdf).

**Initial application** — (Narcolepsy\*) only from a neurologist or respiratory specialist. Approvals valid without further renewal unless notified where the patient suffers from narcolepsy.

Note: \*narcolepsy is not a registered indication for Concerta or Ritalin LA.

MODAFINIL – Special Authority see SA2451 below – Retail pharmacy

Brand switch fee payable (Pharmacode 2704684)	) - see page 281 for details		
Tab 100 mg		30	Modafinil Max

### ► SA2451 Special Authority for Subsidy

**Initial application** only from a neurologist or respiratory specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
  - 1.2 Either:
    - 1.2.1 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
    - 1.2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and

1.3 Either:

1.3.1 An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled and discontinued because of intolerable side effects; or

continued...

Health

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

1.3.2 Methylphenidate and dexamfetamine are contraindicated; or

2 Both:

- Patient meets the Special Authority criteria for methylphenidate hydrochloride or methylphenidate hydrochloride extended-release for narcolepsy; and
- 2.2 Patient is unable to access methylphenidate hydrochloride presentations due to an out of stock (see note).

Note: Criterion 2 is to permit short-term funding to cover an out-of-stock of methylphenidate hydrochloride or methylphenidate hydrochloride extended release.

## **Treatments for Dementia**

DONEPEZIL HYDROCHLORIDE			
* Tab 5 mg	3.70	84	<ul> <li>Ipca-Donepezil</li> </ul>
* Tab 10 mg	5.50	84	✓ Ipca-Donepezil
RIVASTIGMINE - Special Authority see SA1488 below -	Retail pharmacy		
Patch 4.6 mg per 24 hour		30	Rivastigmine Patch
			BNM 5
Patch 9.5 mg per 24 hour		30	Rivastigmine Patch
			<u>BNM 10</u>

## ⇒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.

## **Treatments for Substance Dependence**

BUPRENORPHINE WITH NALOXONE - Special Authority see SA1203 below - Retail pharmacy

<ul> <li>a) No patient co-payment payable</li> <li>b) Safety medicine; prescriber may determine dispensing frequency</li> </ul>		
Tab sublingual 2 mg with naloxone 0.5 mg	28	<ul> <li>Buprenorphine Naloxone BNM</li> </ul>
Tab sublingual 8 mg with naloxone 2 mg34.00	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:

S	Subsidy F	Fully Brand or	
(Manufac	cturer's Price) Subsidi	ised Generic	
	\$ Per	<ul> <li>Manufacturer</li> </ul>	

All of the following:

- 1 Patient is opioid dependent; and
- 2 Patient will not be receiving methadone; and
- 3 Patient is currently enrolled in an opioid substitution treatment program in a service approved by the Ministry of Health; and
- 4 Applicant works in an opioid treatment service approved by the Ministry of Health.

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

All of the following:

- 1 Patient is opioid dependent; and
- 2 Patient has previously trialled but failed detoxification with buprenorphine with naloxone with relapse back to opioid use and another attempt is planned; and
- 3 Patient is currently engaged with an opioid treatment service approved by the Ministry of Health; and
- 4 Applicant works in an opioid treatment service approved by the Ministry of Health.

Renewal — (Maintenance treatment) from any medical practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient is or has been receiving maintenance therapy with buprenorphine with naloxone (and is not receiving methadone); and
- 2 Patient is currently enrolled in an opioid substitution program in a service approved by the Ministry of Health; and
- 3 Applicant works in an opioid treatment service approved by the Ministry of Health or is a medical practitioner authorised by the service to manage treatment in this patient.

Renewal — (Maintenance treatment where the patient has previously had an initial application for detoxification) from any medical practitioner. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 Patient received but failed detoxification with buprenorphine with naloxone; and
- 2 Maintenance therapy with buprenorphine with naloxone is planned (and patient will not be receiving methadone); and
- 3 Patient is currently enrolled in an opioid substitution program in a service approved by the Ministry of Health; and
- 4 Applicant works in an opioid treatment service approved by the Ministry of Health.

### **BUPROPION HYDROCHLORIDE**

Tab modified-release 150 mg	15.00	30	<ul> <li>Zyban</li> </ul>
DISULFIRAM			
Tab 200 mg	236.40	100	<ul> <li>Antabuse</li> </ul>
NALTREXONE HYDROCHLORIDE - Special Authority see SA	1408 below – Reta	ail pharmacy	
Tab 50 mg	77.77	28	<ul> <li>Naltrexone AOP S29</li> </ul>
	83.33	30	✓ Naltraccord
	102.60		✓ Naltrexone Max
			Health S29

(Naltrexone AOP <sup>\$29</sup> Tab 50 mg to be delisted 1 September 2025)

(Naltrexone Max Health S29) Tab 50 mg to be delisted 1 September 2025)

## ⇒SA1408 Special Authority for Subsidy

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

- 1 Patient is currently enrolled in a recognised comprehensive treatment programme for alcohol dependence; and
- 2 Applicant works in or with a community Alcohol and Drug Service contracted to Health NZ or accredited against the New

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

Zealand Alcohol and Other Drug Sector Standard or the National Mental Health Sector Standard.

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

- 1 Compliance with the medication (prescriber determined); and
- 2 Any of the following:
  - 2.1 Patient is still unstable and requires further treatment; or
  - 2.2 Patient achieved significant improvement but requires further treatment; or
  - 2.3 Patient is well controlled but requires maintenance therapy.

#### NICOTINE

- a) Nicotine will not be funded in amounts less than 4 weeks of treatment.
- b) Note: Direct Provision by a pharmacist permitted under the provisions in Part I of Section A.

Patch 7 mg – Up to 28 patch available on a PSO 19.62	28	<ul> <li>Habitrol</li> </ul>
Patch 14 mg – Up to 28 patch available on a PSO21.57	28	<ul> <li>Habitrol</li> </ul>
Patch 14 mg for direct distribution only - [Xpharm]12.49	7	<ul> <li>Habitrol</li> </ul>
Patch 21 mg – Up to 28 patch available on a PSO	28	<ul> <li>Habitrol</li> </ul>
Patch 21 mg for direct distribution only - [Xpharm]13.19	7	<ul> <li>Habitrol</li> </ul>
Lozenge 1 mg – Up to 216 loz available on a PSO22.53	216	<ul> <li>Habitrol</li> </ul>
Lozenge 1 mg for direct distribution only - [Xpharm] 12.89	36	<ul> <li>Habitrol</li> </ul>
Lozenge 2 mg – Up to 216 loz available on a PSO24.68	216	<ul> <li>Habitrol</li> </ul>
Lozenge 2 mg for direct distribution only - [Xpharm] 13.25	36	<ul> <li>Habitrol</li> </ul>
Gum 2 mg (Fruit) – Up to 204 piece available on a PSO23.02	204	<ul> <li>Habitrol</li> </ul>
Gum 2 mg (Fruit) for direct distribution only - [Xpharm]17.57	96	<ul> <li>Habitrol</li> </ul>
Gum 2 mg (Mint) – Up to 204 piece available on a PSO23.02	204	<ul> <li>Habitrol</li> </ul>
Gum 2 mg (Mint) for direct distribution only - [Xpharm]17.57	96	<ul> <li>Habitrol</li> </ul>
Gum 4 mg (Fruit) – Up to 204 piece available on a PSO25.98	204	<ul> <li>Habitrol</li> </ul>
Gum 4 mg (Fruit) for direct distribution only - [Xpharm]23.87	96	<ul> <li>Habitrol</li> </ul>
Gum 4 mg (Mint) – Up to 204 piece available on a PSO25.98	204	<ul> <li>Habitrol</li> </ul>
Gum 4 mg (Mint) for direct distribution only - [Xpharm]23.87	96	<ul> <li>Habitrol</li> </ul>
	Patch 7 mg – Up to 28 patch available on a PSO       19.62         Patch 14 mg – Up to 28 patch available on a PSO       21.57         Patch 14 mg for direct distribution only – [Xpharm]       12.49         Patch 21 mg – Up to 28 patch available on a PSO       24.72         Patch 21 mg for direct distribution only – [Xpharm]       13.19         Lozenge 1 mg – Up to 216 loz available on a PSO       22.53         Lozenge 2 mg – Up to 216 loz available on a PSO       24.68         Lozenge 2 mg for direct distribution only – [Xpharm]       13.25         Gum 2 mg (Fruit) – Up to 204 piece available on a PSO       23.02         Gum 2 mg (Fruit) for direct distribution only – [Xpharm]       17.57         Gum 2 mg (Mint) for direct distribution only – [Xpharm]       17.57         Gum 2 mg (Mint) for direct distribution only – [Xpharm]       17.57         Gum 4 mg (Fruit) – Up to 204 piece available on a PSO       23.02         Gum 4 mg (Fruit) or direct distribution only – [Xpharm]       17.57         Gum 4 mg (Fruit) – Up to 204 piece available on a PSO       23.02         Gum 4 mg (Fruit) for direct distribution only – [Xpharm]       17.57         Gum 4 mg (Fruit) for direct distribution only – [Xpharm]       17.57         Gum 4 mg (Fruit) for direct distribution only – [Xpharm]       25.98         Gum 4 mg (Fruit) for direct distribution only – [Xpharm] <td< th=""><th>Patch 7 mg - Up to 28 patch available on a PSO19.6228Patch 14 mg - Up to 28 patch available on a PSO21.5728Patch 14 mg for direct distribution only - [Xpharm]12.497Patch 21 mg - Up to 28 patch available on a PSO24.7228Patch 21 mg for direct distribution only - [Xpharm]13.197Lozenge 1 mg - Up to 216 loz available on a PSO22.53216Lozenge 1 mg for direct distribution only - [Xpharm]12.8936Lozenge 2 mg - Up to 216 loz available on a PSO24.68216Lozenge 2 mg - Up to 216 loz available on a PSO23.02204Gum 2 mg (Fruit) - Up to 204 piece available on a PSO23.02204Gum 2 mg (Mint) - Up to 204 piece available on a PSO23.02204Gum 2 mg (Mint) - Up to 204 piece available on a PSO23.02204Gum 4 mg (Fruit) - Up to 204 piece available on a PSO23.02204Gum 4 mg (Fruit) - Up to 204 piece available on a PSO25.98204Gum 4 mg (Fruit) - Up to 204 piece available on a PSO25.98204Gum 4 mg (Fruit) - Up to 204 piece available on a PSO25.98204</th></td<>	Patch 7 mg - Up to 28 patch available on a PSO19.6228Patch 14 mg - Up to 28 patch available on a PSO21.5728Patch 14 mg for direct distribution only - [Xpharm]12.497Patch 21 mg - Up to 28 patch available on a PSO24.7228Patch 21 mg for direct distribution only - [Xpharm]13.197Lozenge 1 mg - Up to 216 loz available on a PSO22.53216Lozenge 1 mg for direct distribution only - [Xpharm]12.8936Lozenge 2 mg - Up to 216 loz available on a PSO24.68216Lozenge 2 mg - Up to 216 loz available on a PSO23.02204Gum 2 mg (Fruit) - Up to 204 piece available on a PSO23.02204Gum 2 mg (Mint) - Up to 204 piece available on a PSO23.02204Gum 2 mg (Mint) - Up to 204 piece available on a PSO23.02204Gum 4 mg (Fruit) - Up to 204 piece available on a PSO23.02204Gum 4 mg (Fruit) - Up to 204 piece available on a PSO25.98204Gum 4 mg (Fruit) - Up to 204 piece available on a PSO25.98204Gum 4 mg (Fruit) - Up to 204 piece available on a PSO25.98204

VARENICLINE TARTRATE - Special Authority see SA1845 below - 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		53 OP	<ul> <li>Champix</li> </ul>
Tab 1 mg	17.62	56	<ul> <li>Champix</li> </ul>

### ⇒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

▲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 (Mapufacturada Price)	Subsidy Fully (Manufacturer's Price) Subsidised			
(Manuacturer S Frice)		Subsidised	Generic	
\$	Per	1	Manufacturer	

- 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) \$	Sub Per	osidised ✓	Generic Manufacturer	
Chemotherapeutic Agents					
Alkylating Agents					
BENDAMUSTINE HYDROCHLORIDE – PCT only – Specialist		e SA2398			
Inj 25 mg vial	50.05	1	✔ В	endamustine Sandoz	
	77.00		🗸 R	ibomustin	
Inj 100 mg vial		1	-	endamustine Sandoz	
	308.00		🗸 R	ibomustin	
Inj 1 mg for ECP	<b>0</b> 4 4	1 mg		axter	

### ⇒SA2398 Special Authority for Subsidy

**Initial application** — (CLL\*) only from a relevant specialist or any relevant 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 chronic lymphocytic leukaemia requiring treatment; and
- 2 Patient has ECOG performance status of 0-2; and
- 3 Bendamustine is to be administered at a maximum dose of 100 mg/m<sup>2</sup> on days 1 and 2 every 4 weeks for a maximum of 6 cycles.

Note: Indication marked with a \* includes indications that are unapproved. 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL).

Initial application — (Indolent, Low-grade lymphomas) only from a relevant specialist or any relevant 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 The patient has ECOG performance status of 0-2; and
- 3 Any of the following:
  - 3.1 Both:
    - 3.1.1 Patient is treatment naive; and
    - 3.1.2 Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+); or
  - 3.2 Both:
    - 3.2.1 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen; and
    - 3.2.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
  - 3.3 All of the following:
    - 3.3.1 The patient has not received prior bendamustine therapy; and
    - 3.3.2 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
    - 3.3.3 Patient has had a rituximab treatment-free interval of 12 months or more; or
  - 3.4 Bendamustine is to be administered as monotherapy for a maximum of 6 cycles in rituximab refractory patients.

**Renewal — (Indolent, Low-grade lymphomas)** only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria: Either:

1 Both:

1.1 Patient is refractory to or has relapsed within 12 months of rituximab in combination with bendamustine; and

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

continued...

1.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or

2 Both:

2.1 Patients have not received a bendamustine regimen within the last 12 months; and

2.2 Either:

2.2.1 Both:

- 2.2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
- 2.2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more; or
- 2.2.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.

Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ Waldenstrom's macroglobulinaemia.

**Initial application — (Hodgkin's lymphoma\*)** only from a relevant specialist or any relevant 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			
Tab 2 mg		100	<ul> <li>Myleran</li> </ul>
CARBOPLATIN – PCT only – Specialist			
Inj 10 mg per ml, 45 ml vial		1	<ul> <li>Carboplatin Accord</li> </ul>
			<ul> <li>DBL Carboplatin</li> <li>S29 S29</li> </ul>
	32.59		✓ DBL Carboplatin
	48.50		✓ Carbaccord
Inj 1 mg for ECP	0.06	1 mg	✓ Baxter
CARMUSTINE - PCT only - Specialist		•	
Inj 100 mg vial		1	BiCNU
Inj 100 mg for ECP		100 mg OP	<ul> <li>Baxter</li> </ul>
CHLORAMBUCIL – PCT – Retail pharmacy-Spe		-	
Tab 2 mg		25	<ul> <li>Leukeran FC</li> </ul>
CISPLATIN – PCT only – Specialist			
Inj 1 mg per ml, 50 ml vial		1	<ul> <li>Cisplatin Accord</li> </ul>
3 31- 3	15.00		<ul> <li>Cisplatin Ebewe</li> </ul>
Inj 1 mg per ml, 100 ml vial		1	<ul> <li>Cisplatin Accord</li> </ul>
	21.00		<ul> <li>Cisplatin Ebewe</li> </ul>
	29.66		<ul> <li>DBL Cisplatin</li> </ul>
Inj 1 mg for ECP	0.19	1 mg	<ul> <li>Baxter</li> </ul>
CYCLOPHOSPHAMIDE			
Tab 50 mg – PCT – Retail pharmacy-Specia	alist145.00	50	<ul> <li>Cyclonex</li> </ul>
Inj 1 g vial – PCT – Retail pharmacy-Specia	list47.46	1	Endoxan
	127.80	6	<ul> <li>Cytoxan</li> </ul>
Inj 2 g vial – PCT only – Specialist		1	Endoxan
Inj 1 mg for ECP – PCT only – Specialist	0.05	1 mg	<ul> <li>Baxter</li> </ul>

154 fully subsidised Principal Supply Sole Subsidised Supply

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
IFOSFAMIDE – PCT only – Specialist				
Inj 1 g	96.00	1	✓	Holoxan
Inj 2 g		1		Holoxan
Inj 1 mg for ECP	0.10	1 mg	✓	Baxter
LOMUSTINE – PCT – Retail pharmacy-Specialist				
Cap 40 mg		20	✓	Medac S29
MELPHALAN				
Tab 2 mg – PCT – Retail pharmacy-Specialist		25	1	Alkeran
Inj 50 mg – PCT only – Specialist		1	1	Melpha
, , . , . , . , . , . , . , . , . ,	67.80			Alkeran
OXALIPLATIN – PCT only – Specialist				
Inj 100 mg vial	25.01	1	1	Oxaliplatin Actavis
	2010	•		100
	110.00		1	Oxaliplatin Ebewe
Inj 5 mg per ml, 20 ml vial		1		Alchemy Oxaliplatin
J - 3 - 7 - 8	46.32			Oxaliplatin Accord
Inj 1 mg for ECP	0.35	1 mg	1	Baxter
THIOTEPA – PCT only – Specialist		-		
Inj 15 mg vial	CBS	1	1	Bedford S29
		'		Max Health S29
				THIO-TEPA S29
	398.00			Tepadina
Inj 100 mg vial		1		Max Health S29
Inj 100 mg viai	1,800.00	1		Tepadina
	1,000.00		•	repaulia
Antimetabolites				
AZACITIDINE – PCT only – Specialist – Special Authority see S	A2479 below			
Inj 100 mg vial		1	✓ .	Azacitidine Dr Reddy's
Inj 1 mg for ECP	0.54	1 mg	1	Baxter

#### SA2479 Special Authority for Subsidy

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

1 Any of the following:

- 1.1 The individual has intermediate or high risk MDS based on an internationally recognised scoring system; or
- 1.2 The individual has chronic myelomonocytic leukaemia (based on an intermediate or high risk score from an internationally recognised scoring system or 10%-29% marrow blasts without myeloproliferative disorder); or
- 1.3 The individual has acute myeloid leukaemia according to World Health Organisation Classification (WHO); and
- 2 The individual has an estimated life expectancy of at least 3 months.

Renewal from any relevant practitioner. Approvals valid for 12 months where there is no evidence of disease progression.

ALCIUM FOLINATE Tab 15 mg – PCT – Retail pharmacy-Specialist Inj 3 mg per ml, 1 ml – PCT – Retail pharmacy-Specialist Inj 10 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist Inj 50 mg – PCT – Retail pharmacy-Specialist Inj 10 mg per ml, 10 ml vial – PCT only – Specialist Inj 100 mg – PCT only – Specialist	17.10 7.28 112.20 72.80 9.49 163.35 7.33 94.90	10 5 1 5 10 1 5 1 10	, , , , , , , , , ,	DBL Leucovorin Calcium Hospira Calcium Folinate Sandoz Calcium Folinate Sandoz S29 S29 Eurofolic S29 Leucovorin Pharmacia S29 Calcium Folinate Sandoz Eurofolic S29 Calcium Folinate Ebewe
Inj 3 mg per ml, 1 ml – PCT – Retail pharmacy-Specialist Inj 10 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist Inj 50 mg – PCT – Retail pharmacy-Specialist Inj 10 mg per ml, 10 ml vial – PCT only – Specialist	17.10 7.28 112.20 72.80 9.49 163.35 7.33 94.90	5 1 5 10 1 5 1	, , , , , , , , , ,	Calcium Hospira Calcium Folinate Sandoz Calcium Folinate Sandoz S29 S29 Eurofolic S29 Leucovorin Pharmacia S29 Calcium Folinate Sandoz Eurofolic S29 Calcium Folinate Ebewe
Inj 10 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist Inj 50 mg – PCT – Retail pharmacy-Specialist Inj 10 mg per ml, 10 ml vial – PCT only – Specialist	7.28 112.20 72.80 9.49 163.35 7.33 94.90	1 5 10 1 5 1	, , , , , , ,	Calcium Folinate Sandoz Calcium Folinate Sandoz S29 S29 Eurofolic S29 Leucovorin Pharmacia S29 Calcium Folinate Sandoz Eurofolic S29 Calcium Folinate Ebewe
Inj 50 mg – PCT – Retail pharmacy-Specialist	112.20 72.80 9.49 163.35 7.33 94.90	5 10 1 5 1	5 5 5 5 5	Sandoz Calcium Folinate Sandoz S29 S29 Eurofolic S29 Leucovorin Pharmacia S29 Calcium Folinate Sandoz Eurofolic S29 Calcium Folinate Ebewe
Inj 10 mg per ml, 10 ml vial – PCT only – Specialist	72.80 9.49 163.35 7.33 94.90	10 1 5 1		Sandoz S29 S29 Eurofolic S29 Leucovorin Pharmacia S29 Calcium Folinate Sandoz Eurofolic S29 Calcium Folinate Ebewe
Inj 10 mg per ml, 10 ml vial – PCT only – Specialist	72.80 9.49 163.35 7.33 94.90	10 1 5 1	ע ע ע	Leucovorin Pharmacia 529 Calcium Folinate Sandoz Eurofolic 529 Calcium Folinate Ebewe
Inj 10 mg per ml, 10 ml vial – PCT only – Specialist	9.49 163.35 7.33 94.90	1 5 1	, , ,	Pharmacia S29 Calcium Folinate Sandoz Eurofolic S29 Calcium Folinate Ebewe
	163.35 7.33 94.90	5 1	/ /	Sandoz Eurofolic S29 Calcium Folinate Ebewe
Inj 100 mg – PCT only – Specialist	7.33 94.90	1	~	Calcium Folinate Ebewe
Inj 100 mg – PCT only – Specialist	94.90			Ebewe
		10	~	Lauranuarda
	01 55			Leucovorin Pharmacia S29
Inj 300 mg - PCT only - Specialist	21.55	1	~	Leucovorin DBL S29
	22.51		~	Calcium Folinate Ebewe
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 Ebewe
Inj 10 mg per ml, 100 ml vial - PCT only - Specialist	72.00	1	1	Calcium Folinate Sandoz
	139.48		~	Eurofolic S29
Inj 1 mg for ECP – PCT only – Specialist	0.14	1 mg	~	Baxter
lcium Folinate Sandoz Inj 10 mg per ml, 5 ml vial to be delisted	1 November 20	025)		
Icium Folinate Sandoz S29 929 Inj 10 mg per ml, 5 ml vial to b Icium Folinate Sandoz Inj 10 mg per ml, 10 ml vial to be delisted Icium Folinate Ebewe Inj 100 mg to be delisted 1 November 202 Icium Folinate Ebewe Inj 300 mg to be delisted 1 November 202	1 1 November 2 25)		025)	
alcium Folinate Sandoz Inj 10 mg per ml, 35 ml vial to be delisted		2025)		
Icium Folinate Sandoz S29 <sup>S29</sup> Inj 10 mg per ml, 35 ml vial to Icium Folinate Ebewe Inj 1 g to be delisted 1 November 2025)			2025)	
alcium Folinate Sandoz Inj 10 mg per ml, 100 ml vial to be deliste PECITABINE – Retail pharmacy-Specialist	ed 1 November	· 2025)		
Tab 150 mg	9.80	60	1	Capecitabine Viatris
Tab 500 mg		120		Capecitabine Viatris
ADRIBINE – PCT only – Specialist Inj 1 mg per ml, 10 ml	749.96	1	1	Leustatin
Inj 10 mg for ECP		10 mg O		Baxter

	Subsidy (Manufacturer's Price) Su		Fully Brand or
	(Manufacturer's	Price) Subs Per	sidised Generic Manufacturer
CYTARABINE			
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Speci	alist472.00	5	<ul> <li>Pfizer</li> </ul>
Inj 100 mg per ml, 20 ml vial - PCT - Retail			
pharmacy-Specialist		1	<ul> <li>Cytarabine DBL</li> </ul>
			<ul> <li>Pfizer</li> </ul>
			<ul> <li>Pfizer S29 S29</li> </ul>
Inj 1 mg for ECP – PCT only – Specialist		10 mg	<ul> <li>Baxter</li> </ul>
Inj 100 mg intrathecal syringe for ECP – PCT only – Speci		100 mg OP	<ul> <li>Baxter</li> </ul>
Pfizer S29 🕸 Inj 100 mg per ml, 20 ml vial to be delisted 1 (	October 2025)		
FLUDARABINE PHOSPHATE			
Tab 10 mg – PCT – Retail pharmacy-Specialist		20	<ul> <li>Fludara Oral</li> </ul>
Inj 50 mg vial – PCT only – Specialist		1	<ul> <li>Fludarabine</li> </ul>
			Sagent S29
	634.00	5	<ul> <li>Fludarabine Ebewe</li> </ul>
Inj 50 mg for ECP – PCT only – Specialist		50 mg OP	<ul> <li>Baxter</li> </ul>
Fludarabine Sagent 1 Inj 50 mg vial to be delisted 1 Nover	nber 2025)		
FLUOROURACIL			
Inj 50 mg per ml, 20 ml vial – PCT only – Specialist		1	<ul> <li>Fluorouracil Accord</li> </ul>
Inj 50 mg per ml, 50 ml vial - PCT only - Specialist	14.72	1	<ul> <li>Fluorouracil Accord</li> </ul>
Inj 50 mg per ml, 100 ml vial – PCT only – Specialist		1	<ul> <li>Fluorouracil Accord</li> </ul>
Inj 1 mg for ECP – PCT only – Specialist	0.41	100 mg	<ul> <li>Baxter</li> </ul>
GEMCITABINE HYDROCHLORIDE - PCT only - Specialist			
Inj 43.3 mg per ml (equivalent to 38 mg per ml gemcitabine	e),		
26.3 ml vial	,	1	<ul> <li>DBL Gemcitabine</li> </ul>
Inj 1 g	15.89	1	<ul> <li>Gemcitabine Ebewe</li> </ul>
Inj 1 mg for ECP	0.02	1 mg	<ul> <li>Baxter</li> </ul>
RINOTECAN HYDROCHLORIDE – PCT only – Specialist			
Inj 20 mg per ml, 5 ml vial		1	Accord
	71.44		<ul> <li>Irinotecan Actavis 100</li> </ul>
	100.00		<ul> <li>Irinotecan-Rex</li> </ul>
Inj 1 mg for ECP	0.54	1 mg	<ul> <li>Baxter</li> </ul>
MERCAPTOPURINE			
Tab 50 mg - PCT - Retail pharmacy-Specialist		25	<ul> <li>Puri-nethol</li> </ul>
Oral suspension 20 mg per ml – Retail pharmacy-Specialis			
Special Authority see SA1725 below		100 ml OP	<ul> <li>Allmercap</li> </ul>
			✓ Xaluprine S29

## ➡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.

	Subsidy		Fully	Brand or
	Manufacturer's Pr \$	Per Subs	sidised	Generic Manufacturer
ETHOTBEXATE	•			
<ul> <li>Tab 2.5 mg – PCT – Retail pharmacy-Specialist</li> </ul>	7 80	90	1	Trexate
<ul> <li>Tab 2.5 mg – PCT – Retail pharmacy-Specialist</li> </ul>		90		Trexate
<ul> <li>Inj 2.5 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist</li> </ul>		5		Methotrexate DBL
<ul> <li>Inj 7.5 mg prefilled syringe</li> </ul>		1		Methotrexate
		I	•	Sandoz
k Inj 10 mg prefilled syringe	19.09	1	1	Methotrexate
			•	Sandoz
Inj 15 mg prefilled syringe	24 53	1	1	Methotrexate
			•	Sandoz
k Inj 20 mg prefilled syringe	16.64	1	1	Methotrexate
Inj 20 mg premied synnge	10.04	I	•	Sandoz
k Ini OE ma profilled ouringe	00.70	4		
Inj 25 mg prefilled syringe		1	v	Methotrexate Sandoz
	55.00			Sandoz Mathatravata
Inj 30 mg prefilled syringe	55.00	1	~	Methotrexate
		_		Sandoz
Inj 25 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialis	t30.00	5	~	Methotrexate DBL
				Onco-Vial
Inj 25 mg per ml, 20 ml vial – PCT – Retail pharmacy-Speciali	st45.00	1	~	DBL Methotrexate
				Onco-Vial
Inj 100 mg per ml, 10 ml – PCT – Retail pharmacy-Specialist.	25.00	1	1	Methotrexate Ebewe
k Inj 100 mg per ml, 50 ml vial – PCT – Retail				
pharmacy-Specialist	67.99	1	1	Methotrexate Ebewe
Inj 1 mg for ECP – PCT only – Specialist	0.06	1 mg	1	Baxter
Inj 5 mg intrathecal syringe for ECP – PCT only – Specialist	4.73	5 mg OP	✓	Baxter
PEMETREXED – PCT only – Specialist		-		
Inj 100 mg vial	8 99	1	1	Pemetrexed-AFT
	60.89	•		Juno Pemetrexed
Inj 500 mg vial		1		Pemetrexed-AFT
	217.77	·		Juno Pemetrexed
Inj 1 mg for ECP		1 mg		Baxter
		1.119		Buxton
HIOGUANINE – PCT – Retail pharmacy-Specialist Tab 40 mg	106.01	25		Lanvis
Tab 40 mg	120.31	20	•	Lativis
Other Cytotoxic Agents				
MSACRINE – PCT only – Specialist				
Inj 50 mg per ml, 1.5 ml ampoule	4,736.00	6	1	Amsidine S29
Inj 75 mg		5		AmsaLyo S29
		-		,
NAGRELIDE HYDROCHLORIDE – PCT – Retail pharmacy-Spe		100	./	Agnulin
Cap 0.5 mg	1,1/5.8/	100	v	Agrylin
RSENIC TRIOXIDE – PCT only – Specialist				
Inj 1 mg per ml, 10 ml vial		10		Phenasen
Inj 10 mg for ECP		10 mg OP	1	Baxter
BLEOMYCIN SULPHATE – PCT only – Specialist				
	105 16	1	1	DBL Bleomycin
Inj 15,000 iu, vial	100.10	1		
Inj 15,000 iu, vial	103.10			Sulfate

	Subsidy		Fully Brand or
	(Manufacturer's I		idised Generic
	\$	Per	<ul> <li>Manufacturer</li> </ul>
BORTEZOMIB - PCT only - Specialist - Special Authority see S	A2355 below		
Inj 3.5 mg vial	74.93	1	<ul> <li>DBL Bortezomib</li> </ul>
Inj 1 mg for ECP	22.26	1 mg	<ul> <li>Baxter</li> </ul>
➡SA2355 Special Authority for Subsidy			
Initial application - (plasma cell dyscrasia) from any relevan	t practitioner. A	pprovals valid w	vithout further renewal unless
notified where the patient has plasma cell dyscrasia, not including	g Waldenström i	nacroglobulinae	emia, requiring treatment.
DACARBAZINE – PCT only – Specialist			
Inj 200 mg vial	72.11	1	<ul> <li>DBL Dacarbazine</li> </ul>
Inj 200 mg for ECP		200 mg OP	<ul> <li>Baxter</li> </ul>
DACTINOMYCIN [ACTINOMYCIN D] - PCT only - Specialist		-	
Inj 0.5 mg vial	255.00	1	<ul> <li>Cosmegen</li> </ul>
Inj 0.5 mg for ECP		0.5 mg OP	✓ Baxter
	200100	olo llig ol	24.00
DAUNORUBICIN – PCT only – Specialist Inj 2 mg per ml, 10 ml	171.02	1	✓ Pfizer
		20 mg OP	✓ Baxter
Inj 20 mg for ECP		20 mg OF	
DOCETAXEL – PCT only – Specialist	10 75		
Inj 20 mg		1	<ul> <li>Docetaxel Sandoz</li> </ul>
Inj 10 mg per ml, 8 ml vial		1	<ul> <li>DBL Docetaxel</li> </ul>
Inj 20 mg per ml, 4 ml vial		1	<ul> <li>Docetaxel</li> </ul>
			Accord S29
Inj 80 mg		1	<ul> <li>Docetaxel Sandoz</li> </ul>
Inj 1 mg for ECP	0.35	1 mg	Baxter
DOXORUBICIN HYDROCHLORIDE - PCT only - Specialist			
Inj 2 mg per ml, 5 ml vial	10.00	1	<ul> <li>Doxorubicin Ebewe</li> </ul>
Inj 2 mg per ml, 25 ml vial	11.50	1	<ul> <li>Doxorubicin Ebewe</li> </ul>
	17.00		Arrow-Doxorubicin
Inj 2 mg per ml, 50 ml vial	23.00	1	<ul> <li>Doxorubicin Ebewe</li> </ul>
Inj 2 mg per ml, 100 ml vial	65.00	1	Arrow-Doxorubicin
	69.99		<ul> <li>Doxorubicin Ebewe</li> </ul>
Inj 1 mg for ECP	0.35	1 mg	<ul> <li>Baxter</li> </ul>
EPIRUBICIN HYDROCHLORIDE – PCT only – Specialist			
Inj 2 mg per ml, 5 ml vial	25.00	1	<ul> <li>Epirubicin Ebewe</li> </ul>
Inj 2 mg per ml, 25 ml vial		1	<ul> <li>Epirubicin Ebewe</li> </ul>
Inj 2 mg per ml, 100 ml vial		1	<ul> <li>Epirubicin Ebewe</li> </ul>
Inj 1 mg for ECP	0.50	1 mg	<ul> <li>Baxter</li> </ul>
ETOPOSIDE			
Cap 50 mg – PCT – Retail pharmacy-Specialist	340.73	20	<ul> <li>Vepesid</li> </ul>
Cap 100 mg – PCT – Retail pharmacy-Specialist	340.73	10	<ul> <li>Vepesid</li> </ul>
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Special	ist7.90	1	Rex Medical
Inj 1 mg for ECP – PCT only – Specialist	0.09	1 mg	<ul> <li>Baxter</li> </ul>
ETOPOSIDE PHOSPHATE – PCT only – Specialist			
Inj 100 mg (of etoposide base)	40.00	1	<ul> <li>Etopophos</li> </ul>
Inj 1 mg (of etoposide base) for ECP		1 mg	<ul> <li>Baxter</li> </ul>
HYDROXYUREA [HYDROXYCARBAMIDE] - PCT - Retail phar		t	
Cap 500 mg		100	<ul> <li>Devatis</li> </ul>
IBRUTINIB – Special Authority see SA2480 on the next page – F			
Tab 140 mg		30	<ul> <li>Imbruvica</li> </ul>
Tab 420 mg		30	✓ Imbruvica
	0,002.00	00	

▲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

Subsid		
(Manufacture		d Generic
\$	Per	Manufacturer

### ⇒SA2480 Special Authority for Subsidy

**Initial application** — (chronic lymphocytic leukaemia (CLL)) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Individual has chronic lymphocytic leukaemia (CLL) requiring therapy; and
- 2 Individual has not previously received funded ibrutinib; and
- 3 Ibrutinib is to be used as monotherapy; and
- 4 Any of the following:
  - 4.1 Both:
    - 4.1.1 There is documentation confirming that the individual has 17p deletion or TP53 mutation; and
    - 4.1.2 Individual has experienced intolerable side effects with venetoclax monotherapy; or
  - 4.2 All of the following:
    - 4.2.1 Individual has received at least one prior immunochemotherapy for CLL; and
    - 4.2.2 Individual's CLL has relapsed; and
    - 4.2.3 Individual has experienced intolerable side effects with venetoclax in combination with rituximab regimen; or
  - 4.3 Individual's CLL is refractory to or has relapsed following a venetoclax regimen.

Renewal — (chronic lymphocytic leukaemia (CLL)) from any relevant practitioner. Approvals valid for 12 months where there is no evidence of disease progression.

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

### IDARUBICIN HYDROCHLORIDE

Inj 5 mg vial – PCT only – Specialist Inj 10 mg vial – PCT only – Specialist Inj 1 mg for ECP – PCT only – Specialist	233.64 25.77	1 1 1 mg	<ul><li>✓ Zavedos</li><li>✓ Zavedos</li><li>✓ Baxter</li></ul>
LENALIDOMIDE (VIATRIS) - Special Authority see SA23	53 below – Retail pharm	acy	
Cap 5 mg		21	✓ <u>Lenalidomide</u> <u>Viatris</u>
Cap 10 mg		21	✓ <u>Lenalidomide</u> <u>Viatris</u>
Cap 15 mg	62.13	21	✓ <u>Lenalidomide</u> <u>Viatris</u>
Cap 25 mg	65.09	21	<ul> <li>Lenalidomide</li> <li>Viatris</li> </ul>

### ➡SA2353 Special Authority for Subsidy

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

1 Patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment; and

2 Patient is not refractory to prior lenalidomide use.

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

Both:

- 1 Patient has low or intermediate-1 risk myelodysplastic syndrome (based on IPSS or an IPSS-R score of less than 3.5) associated with a deletion 5q cytogenetic abnormality; and
- 2 Patient has transfusion-dependent anaemia.

Renewal — (Myelodysplastic syndrome) from any relevant practitioner. Approvals valid for 12 months for applications meeting

	Subsidy (Manufacturer's Price) \$	) Per	Fully Subsidised	Generic
continued				
the following criteria: Both:				
<ol> <li>Patient has not needed a transfusion in the last 4 months;</li> </ol>	and			
<ul><li>2 No evidence of disease progression.</li></ul>	anu			
MESNA				
Tab 400 mg – PCT – Retail pharmacy-Specialist	314.00	50	1	Uromitexan
Tab 600 mg – PCT – Retail pharmacy-Specialist		50	✓	Uromitexan
Inj 100 mg per ml, 4 ml ampoule – PCT only – Specialist		15		Uromitexan
Inj 100 mg per ml, 10 ml ampoule - PCT only - Specialist		15		Uromitexan
Inj 1 mg for ECP – PCT only – Specialist	2.96	100 m	g 🗸	Baxter
MITOMYCIN C – PCT only – Specialist				
Inj 5 mg vial	517.65	1	~	Accord S29
			✓	Mitomycin
				(Fresenius Kabi) <sup>S29</sup>
	526.00		~	Mitomycin
				(Sagent) S29
Inj 20 mg vial	1,250.00	1	1	Omegapharm S29
			~	Teva
Inj 1 mg for ECP		1 mg	✓	Baxter
(Omegapharm S29 Inj 20 mg vial to be delisted 1 October 2025)				
MITOZANTRONE – PCT only – Specialist				
Inj 2 mg per ml, 10 ml vial		1	1	Mitozantrone Ebewe
Inj 1 mg for ECP	5.51	1 mg	1	Baxter
NIRAPARIB – Special Authority see SA2325 below – Retail phan Wastage claimable	macy			
Tab 100 mg	13,393.50	84	1	Zejula
Cap 100 mg	8,929.84	56	1	Zejula

#### ➡SA2325 Special Authority for Subsidy

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

- 1 Patient has advanced high-grade serous\* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
- 2 Patient has received at least one line\*\* of treatment with platinum-based chemotherapy; and
- 3 Patient has experienced a partial or complete response to the preceding treatment with platinum-based chemotherapy; and
- 4 Patient has not previously received funded treatment with a PARP inhibitor; and
- 5 Either:
  - 5.1 Treatment will be commenced within 12 weeks of the patient's last dose of the preceding platinum-based regimen; or
  - 5.2 Patient commenced treatment with niraparib prior to 1 May 2024; and
- 6 Treatment to be administered as maintenance treatment; and
- 7 Treatment not to be administered in combination with other chemotherapy.

**Renewal** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

1 No evidence of progressive disease; and

continued...

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

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

Subs	sidy F	ully Brand o	r
(Manufactur	rer's Price) Subsidi:	sed Generic	
\$	6 Per	<ul> <li>Manufac</li> </ul>	cturer

continued...

- 2 Treatment to be administered as maintenance treatment; and
- 3 Treatment not to be administered in combination with other chemotherapy; and
- 4 Either:
  - 4.1 Treatment with niraparib to cease after a total duration of 36 months from commencement; or
  - 4.2 Treatment with niraparib is being used in the second-line or later maintenance setting.

Notes: \* "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component. \*\*A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments

OLAPARIB - Retail pharmacy-Specialist - Special Authority see SA2163 below

Tab 100 mg	 ·····	 	 	1.00	56	🗸 Lynparza
Tab 150 mg	 	 	 	1.00	56	<ul> <li>Lynparza</li> </ul>

### ➡SA2163 Special Authority for Subsidy

Initial application — (Ovarian cancer) only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 Patient has a high-grade serous\* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
- 2 There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
- 3 Either:
  - 3.1 All of the following:
    - 3.1.1 Patient has newly diagnosed, advanced disease; and
    - 3.1.2 Patient has received one line\*\* of previous treatment with platinum-based chemotherapy; and
    - 3.1.3 Patient's disease must have experienced a partial or complete response to the first-line platinum-based regimen; or
  - 3.2 All of the following:
    - 3.2.1 Patient has received at least two lines\*\* of previous treatment with platinum-based chemotherapy; and
    - 3.2.2 Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line\*\* of platinum-based chemotherapy; and
    - 3.2.3 Patient's disease must have experienced a partial or complete response to treatment with the immediately preceding platinum-based regimen; and
    - 3.2.4 Patient has not previously received funded olaparib treatment; and
- 4 Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
- 5 Treatment to be administered as maintenance treatment; and
- 6 Treatment not to be administered in combination with other chemotherapy.

Renewal — (Ovarian cancer) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- - 1 Treatment remains clinically appropriate and patient is benefitting from treatment; and
  - 2 Either:
    - 2.1 No evidence of progressive disease; or
    - 2.2 Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion; and
  - 3 Treatment to be administered as maintenance treatment; and
  - 4 Treatment not to be administered in combination with other chemotherapy; and
  - 5 Either:
    - 5.1 Both:

Subsidy	l	-ully	Brand or
Manufacturer's Price)	Subsid	ised	Generic
 \$	Per	1	

continued...

- 5.1.1 Patient has received one line\*\* of previous treatment with platinum-based chemotherapy; and
- 5.1.2 Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years; or
- 5.2 Patient has received at least two lines\*\* of previous treatment with platinum-based chemotherapy.

Notes: \*Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component. \*\*A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

PAGLITAXEL – PGT only – Specialist			
Inj 30 mg		5	Paclitaxel Ebewe
Inj 6 mg per ml, 16.7 ml vial		1	<ul> <li>Anzatax</li> </ul>
	24.00		Paclitaxel Ebewe
	91.67		Paclitaxel Actavis
Inj 150 mg		1	Paclitaxel Ebewe
, ,	137.50		<ul> <li>Anzatax</li> </ul>
			Paclitaxel Actavis
Inj 6 mg per ml, 50 ml vial		1	<ul> <li>Anzatax</li> </ul>
	44.00		Paclitaxel Ebewe
	275.00		Paclitaxel Actavis
Inj 1 mg for ECP	0.17	1 mg	<ul> <li>Baxter</li> </ul>
PEGASPARGASE - PCT only - Special Authority se	e SA1979 below		
Inj 750 iu per ml, 5 ml vial		1	<ul> <li>Oncaspar LYO</li> </ul>
- CA1070 Onesial Authority for Outside			

### ⇒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] - PCT only - Specialist

Inj 10 mg	CBS	1	<ul> <li>Nipent S29</li> </ul>
POMALIDOMIDE - Special Authority see SA2354 on the	e next page – Retail pharn	nacy	
Cap 1 mg		14	Pomolide
	71.18	21	<ul> <li>Pomolide</li> </ul>
Cap 2 mg		14	Pomolide
	142.35	21	Pomolide
Cap 3 mg		14	Pomolide
	213.53	21	Pomolide
Cap 4 mg		14	Pomolide
	284.71	21	Pomolide

▲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	Fu	ly Brand or
(N	Ianufacturer's Price)	Subsidise	ed Generic
	\$	Per	Manufacturer

### ⇒SA2354 Special Authority for Subsidy

**Initial application** — (Relapsed/refractory plasma cell dyscrasia) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has relapsed or refractory plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment; and
- 2 Patient has not received prior funded pomalidomide.

Renewal — (Relapsed/refractory plasma cell dyscrasia) from any relevant practitioner. Approvals valid for 12 months where there is no evidence of disease progression.

Cap 50 mg		50	<ul> <li>Natulan S29</li> </ul>
EMOZOLOMIDE - Special Authority see SA2275 below	<ul> <li>Retail pharmacy</li> </ul>		
Cap 5 mg	9.13	5	<ul> <li>Temaccord</li> </ul>
			<ul> <li>Temozolomide-</li> </ul>
			Taro S29
Cap 20 mg		5	Temaccord
	18.30		<ul> <li>Apo-Temozolomide</li> </ul>
Cap 100 mg		5	<ul> <li>Temaccord</li> </ul>
	40.20		<ul> <li>Apo-Temozolomide</li> </ul>
Cap 140 mg		5	<ul> <li>Temaccord</li> </ul>
Cap 250 mg		5	<ul> <li>Temaccord</li> </ul>

#### ➡SA2275 Special Authority for Subsidy

**Initial application** — (gliomas) only from a relevant specialist. Approvals valid for 12 months where the patient has a glioma. **Renewal** — (gliomas) only from a relevant specialist. Approvals valid for 12 months where treatment remains appropriate and patient is benefitting from treatment.

**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/m<sup>2</sup> per day; and
- 4 Temozolomide to be discontinued at disease progression.

Renewal — (neuroendocrine tumours) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

**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 — (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.

	Subsidy (Manufacturer's Price) \$	S Per	Fully ubsidised	Brand or Generic Manufacturer
THALIDOMIDE – Retail pharmacy-Specialist – Special Authority	see SA2356 below			
Cap 50 mg		28	🗸 T	halomid
Cap 100 mg	756.00	28	🗸 T	halomid

### ⇒SA2356 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months where the patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment.

Renewal from any relevant practitioner. 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.

#### TRETINOIN

Cap 10 mg – PCT – Retail pharmacy-Specialist	479.50	100	<ul> <li>Vesanoid</li> </ul>
VENETOCLAX - Retail pharmacy-Specialist - Special Authority se	e SA2481 below		
Tab 14 × 10 mg, 7 × 50 mg, 21 × 100 mg	1,771.86	42 OP	<ul> <li>Venclexta</li> </ul>
Tab 10 mg		2 OP	<ul> <li>Venclexta</li> </ul>
Tab 50 mg	239.44	7 OP	<ul> <li>Venclexta</li> </ul>
Tab 100 mg - Wastage claimable	8,209.41	120	<ul> <li>Venclexta</li> </ul>

#### ⇒SA2481 Special Authority for Subsidy

**Initial application** — (relapsed/refractory chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 7 months for applications meeting the following criteria:

All of the following:

- 1 Individual has chronic lymphocytic leukaemia requiring treatment; and
- 2 Individual has received at least one prior therapy for chronic lymphocytic leukaemia; and
- 3 Individual has not previously received funded venetoclax; and
- 4 The individual's disease has relapsed; 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 Individual has an ECOG performance status of 0-2.

Renewal — (relapsed/refractory chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Treatment remains clinically appropriate and the individual 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\*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Individual has previously untreated chronic lymphocytic leukaemia; and
- 2 There is documentation confirming that individual has 17p deletion by FISH testing or TP53 mutation by sequencing; and
- 3 Individual has an ECOG performance status of 0-2.

Renewal — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation\*) from any relevant practitioner. 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

**Initial application — (previously untreated acute myeloid leukaemia)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Subsidy (Manufacturer's Price)	5	Fully Subsidised	Brand or Generic
\$	Per	1	Manufacturer

continued...

Either:

- 1 The individual is currently on treatment with venetoclax and met all remaining special authority criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Individual has previously untreated acute myeloid leukaemia (see note a), according to World Health Organization (WHO) Classification; and
  - 2.2 Venetoclax not to be used in combination with standard intensive remission induction chemotherapy; and
  - 2.3 Venetoclax to be used in combination with azacitidine or low dose cytarabine.

Renewal — (previously untreated acute myeloid leukaemia) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

Notes:

- a) 'Acute myeloid leukaemia' includes myeloid sarcoma\*
- b) Indications marked with \* are Unapproved indications

VINBLASTINE SULPHATE

lnj 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	<ul> <li>Baxter</li> </ul>
VINCRISTINE SULPHATE		
Inj 1 mg per ml, 1 ml vial – PCT – Retail pharmacy-Specialist74.52	5	<ul> <li>DBL Vincristine Sulfate</li> </ul>
Inj 1 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist 102.73	5	<ul> <li>DBL Vincristine Sulfate</li> </ul>
Inj 1 mg for ECP – PCT only – Specialist12.60	1 mg	<ul> <li>Baxter</li> </ul>
VINORELBINE		
Cap 20 mg	1	<ul> <li>Vinorelbine Te Arai</li> </ul>
Cap 30 mg	1	<ul> <li>Vinorelbine Te Arai</li> </ul>
Cap 80 mg60.00	1	Vinorelbine Te Arai
Inj 10 mg per ml, 1 ml vial – PCT only – Specialist	1	<ul> <li>Vinorelbine Ebewe</li> </ul>
Inj 10 mg per ml, 5 ml vial – PCT only – Specialist	1	✓ Navelbine S29 S29
210.00		<ul> <li>Vinorelbine Ebewe</li> </ul>
Inj 1 mg for ECP – PCT only – Specialist	1 mg	✓ Baxter

## Protein-tyrosine Kinase Inhibitors

ALECTINIB - Retail pharmacy-Specialist - Special Authorit	ty see SA1870 below		
Wastage claimable	-		
Cap 150 mg	7,935.00	224	<ul> <li>Alecensa</li> </ul>

### ► SA1870 Special Authority for Subsidy

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

All of the following:

- 1 Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer; and
- 2 There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test; and
- 3 Patient has an ECOG performance score of 0-2.

Renewal only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 No evidence of progressive disease according to RECIST criteria; and
- 2 The patient is benefitting from and tolerating treatment.

	Subsidy (Manufacturer's Price) \$	Per	Full Subsidise	d G	rand or ieneric lanufacturer
AXITINIB – Special Authority see SA2458 below – Retail pharma	асу				
Wastage claimable					
Tab 1 mg		28	✓	' Inlyt	a
Tab 5 mg	2,682.00	28	✓	' Inlyt	a
SA2458 Special Authority for Subsidy					
Initial application from any relevant practitioner. Approvals valid	d for 4 months for ap	olicat	ions meet	ing the	e following criteria:
All of the following:				Ũ	°,
1 The patient has metastatic renal cell carcinoma; and					

- 2 The disease is of predominant clear cell histology; and
- 3 The patient has documented disease progression following one previous line of treatment; and
- 4 The patient has ECOG performance status of 0-2.

Renewal from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression...

CRIZOTINIB – Special Authority see SA2459 below – Retail pharmacy

Cap 200 mg	7,250.00	60	<ul> <li>Xalkori</li> </ul>
Cap 250 mg	7,250.00	60	<ul> <li>Xalkori</li> </ul>

#### ⇒SA2459 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 6 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; and
- 2 There is documentation confirming that the patient has a ROS1 rearrangement using an appropriate ROS1 test; and
- 3 Patient has ECOG performance score of 0-3; and
- 4 Baseline measurement of overall tumour burden is documented clinically and radiologically.

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

- 1 Response to treatment has been determined by comparable radiological assessment following the most recent treatment period; and
- 2 No evidence of disease progression..

DABRAFENIB - Special Authority see SA2494 below - Retail pharmacy

Cap 50 mg	6,320.86	120	🗸 Tafinlar
Cap 75 mg	9,481.29	120	🗸 Tafinlar

#### ⇒SA2494 Special Authority for Subsidy

**Initial application** — (stage III or IV resected melanoma - adjuvant) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a); or

2.1.2 Both:

- 2.1.2.1 The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor; and
- 2.1.2.2 Adjuvant treatment with dabrafenib is required; and
- 2.2 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma; and
- 2.3 Treatment must be adjuvant to complete surgical resection; and
- 2.4 Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and

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

#### continued...

- 2.5 The individual has a confirmed BRAF mutation; and
- 2.6 Dabrafenib must be administered in combination with trametinib; and
- 2.7 The individual has ECOG performance score 0-2.

Notes:

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

Renewal — (stage III or IV resected melanoma - adjuvant) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

- 1 All of the following:
  - 1.1 No evidence of disease recurrence; and
  - 1.2 Dabrafenib must be administered in combination with trametinib; and
  - 1.3 Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadjuvant treatment; or
- 2 All of the following:
  - 2.1 The individual has received adjuvant treatment with a BRAF/MEK inhibitor; and
  - 2.2 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
  - 2.3 The individual meets initial application criteria for dabrafenib for unresectable or metastatic melanoma; or
- 3 All of the following:
  - 3.1 The individual has received adjuvant treatment with a BRAF/MEK inhibitor; and
  - 3.2 The individual has received a BRAF/MEK inhibitor for unresectable or metastatic melanoma; and
  - 3.3 The individual meets renewal criteria for dabrafenib for unresectable or metastatic melanoma.

Initial application — (unresectable or metastatic melanoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
  - 2.2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
  - 2.3 The individual has ECOG performance score 0-2; and
  - 2.4 The individual has confirmed BRAF mutation; and
  - 2.5 Dabrafenib must be administered in combination with trametinib; and
  - 2.6 Any of the following:
    - 2.6.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
    - 2.6.2 The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor; or
    - 2.6.3 All of the following:
      - 2.6.3.1 The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor; and
      - 2.6.3.2 The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor; and
      - 2.6.3.3 The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor.

**Renewal — (unresectable or metastatic melanoma)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

1 Any of the following:

<ul> <li>continued</li> <li>1.1 The individual's disease has had a complete respondent of the individual's disease has had a partial respondent of the individual has stable disease with treatment and the individual has stable disease has had a partial respondent in the individual has stable disease with treatment and the individual has stable disease has had a partial respondent in the individual has stable disease with treatment and the individual</li></ul>	se to treatment; or ; and mined by comparable n armacy	adiologio	cassessm	nent following the most
DASATINIB – Special Authority see SA2385 below – Retail ph Wastage claimable Tab 20 mg Tab 50 mg				
Wastage claimable Tab 20 mg Tab 50 mg				
Tab 20 mg Tab 50 mg				
5		60	🗸 D	asatinib-Teva
Tab 70 mg		60		asatinib-Teva
	415.75	60	✓ □	asatinib-Teva
<ul> <li>2 The patient has a diagnosis of Philadelphia chromosom</li> <li>3 Both:</li> <li>3.1 The patient has a diagnosis of CML in chronic pl</li> <li>3.2 Any of the following:</li> <li>3.2.1 Patient has documented treatment failure</li> <li>3.2.2 Patient has experienced treatment-limitin</li> <li>3.2.3 Patient has high-risk chronic-phase CML</li> </ul>	nase; and * with imatinib; or g toxicity with imatinib   defined by the Sokal o	precludir r EURO	ng further scoring s	treatment with imatinib; ystem.
Renewal only from a haematologist or Practitioner on the recon applications meeting the following criteria: Both:	mmendation of a naem	atologis	t. Approv	ais valid for 6 months foi
1 Lack of treatment failure while on dasatinib*; and	the last of the state of the			
2 Dasatinib treatment remains appropriate and the patient	v	tment.		
Note: *treatment failure for CML as defined by Leukaemia Net				
RLOTINIB – Retail pharmacy-Specialist – Special Authority s Tab 100 mg		30		lchemy
Tab 100 mg		30 30		lchemy
	I I I I I I I I I I I I I I I I I I I			<u></u>
<b></b>	alid for 4 months for ap	plication	s meeting	the following criteria:

- 3 Any of the following:
  - 3.1 Patient is treatment naive; or
  - 3.2 Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results; or
  - 3.3 Both:
    - 3.3.1 The patient has discontinued osimertinib or gefitinib due to intolerance; and
    - 3.3.2 The cancer did not progress while on osimertinib or gefitinib.

Renewal from any relevant practitioner. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

GEFITINIB - Retail pharmacy-Specialist - Special Authority	see SA2423 on the nex	d page	
Tab 250 mg	918.00	30	🗸 Iressa

169

	Subsidy (Manufacturer's Pric		Fully Subsidised	Brand or Generic
	\$	Per		Manufacturer
SA2423 Special Authority for Subsidy				
<b>nitial application</b> from any relevant practitioner. Approve All of the following:	als valid for 4 months for a	pplicat	ions meeting	the following criteria:
<ol> <li>Patient has locally advanced, or metastatic, unrese</li> <li>Any of the following:</li> </ol>	ectable, non-squamous No	n Sma	II Cell Lung (	Cancer (NSCLC); and
2.1 Patient is treatment naive; or				
<ul><li>2.2 Patient has received prior treatment in the a</li><li>2.3 Both:</li></ul>	adjuvant setting and/or whi	le awa	iting EGFR r	esults; or
<ul><li>2.3.1 The patient has discontinued osimer</li><li>2.3.2 The cancer did not progress whilst operation</li></ul>			e; and	
3 There is documentation confirming that disease ex	presses activating mutatio	ns of E	GFR.	
Renewal from any relevant practitioner. Approvals valid f ccan) indicates NSCLC has not progressed.	or 6 months where radiolo	gical as	ssessment (	preferably including CT
MATINIB MESILATE				
₭ Cap 100 mg		60	✓	matinib-Rex
🖌 Cap 400 mg	69.76	30	✓ 1	matinib-Rex
ENVATINIB - Special Authority see SA2442 below - Re	etail pharmacy			
Wastage claimable				
Cap 4 mg	3,407.40	30	-	.envima
Cap 10 mg	3,407.40	30	✓ L	.envima
SA2442 Special Authority for Subsidy				
nitial application — (thyroid cancer) from any relevant	practitioner. Approvals va	alid for	6 months fo	r applications meeting the
ollowing criteria:				
ither:				
<ol> <li>Patient is currently on treatment with lenvatinib and</li> <li>All of the following:</li> </ol>	d met all remaining criteria	prior to	o commencir	ng treatment; or
2.1 The patient has locally advanced or metasta	atic differentiated thyroid c	ancer;	and	

- 2.2 Either:
  - 2.2.1 Patient must have symptomatic progressive disease prior to treatment; or
  - 2.2.2 Patient must progressive disease at critical anatomical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures; and
- 2.3 Any of the following:
  - 2.3.1 A lesion without iodine uptake in a RAI scan; or
  - 2.3.2 Receiving cumulative RAI greater than or equal to 600 mCi; or
  - 2.3.3 Experiencing disease progression after a RAI treatment within 12 months; or
  - 2.3.4 Experiencing disease progression after two RAI treatments administered within 12 months of each other; and
- 2.4 Patient has thyroid stimulating hormone (TSH) adequately supressed; and
- 2.5 Patient is not a candidate for radiotherapy with curative intent; and
- 2.6 Surgery is clinically inappropriate; and
- 2.7 Patient has an ECOG performance status of 0-2.

Renewal — (thyroid cancer) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

**Initial application** — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

Sub	bsidy	Fully	Brand or
(Manufactu	urer's Price) Subsid	dised	Generic
	\$ Per	1	Manufacturer

continued...

- 1 Patient has unresectable hepatocellular carcinoma; and
- 2 Patient has preserved liver function (Childs-Pugh A); and
- 3 Transarterial chemoembolisation (TACE) is unsuitable; and
- 4 Patient has an ECOG performance status of 0-2; and
- 5 Either:
  - 5.1 Patient has not received prior systemic therapy for their disease in the palliative setting; or
  - 5.2 Both:
    - 5.2.1 Patient has experienced treatment-limiting toxicity from treatment with atezolizumab with bevacizumab; and
    - 5.2.2 No disease progression since initiation of atezolizumab with bevacizumab.

Renewal — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

Initial application — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has metastatic renal cell carcinoma; and
  - 1.2 The disease is of predominant clear-cell histology; and
  - 1.3 The patient has documented disease progression following one previous line of treatment; and
  - 1.4 The patient has an ECOG performance status of 0-2; and
  - 1.5 Lenvatinib is to be used in combination with everolimus; or
- 2 All of the following:
  - 2.1 Patient has received funded treatment with nivolumab for the second line treatment of metastatic renal cell carcinoma; and
  - 2.2 Patient has experienced treatment limiting toxicity from treatment with nivolumab; and
  - 2.3 Lenvatinib is to be used in combination with everolimus; and
  - 2.4 There is no evidence of disease progression.

Renewal — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

MIDOSTAURIN – PCT only – Special Authority see SA2342 below

Cap 25 mg...... 10,981.00 56 🖌 Rydapt

# ► SA2342 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria: All of the following:

- 1 Patient has a diagnosis of acute myeloid leukaemia; and
- 2 Condition must be FMS tyrosine kinase 3 (FLT3) mutation positive; and
- 3 Patient must not have received a prior line of intensive chemotherapy for acute myeloid leukaemia; and
- 4 Patient is to receive standard intensive chemotherapy in combination with midostaurin only; and
- 5 Midostaurin to be funded for a maximum of 4 cycles.

NILOTINIB - Special Authority see SA2301 below - Retail pharmacy

Cap 150 mg	1,680.00	120	🗸 Tasigna
Cap 200 mg6	6,532.00	120	🗸 Tasigna

### ⇒SA2301 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	ce)	Subsidised	Generic
\$	Pei	r 🖌	Manufacturer

continued...

- 1 Patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis, high risk chronic phase, or in chronic phase; and
- 2 Either:
  - 2.1 Patient has documented CML treatment failure\* with a tyrosine kinase inhibitor (TKI); or
  - 2.2 Patient has experienced treatment limiting toxicity with a tyrosine kinase inhibitor (TKI) precluding further treatment; 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.

OSIMERTINIB - Special Authority see SA2418 below - Retail pharmacy

Tab 40 mg		30	🗸 Tagrisso
Tab 80 mg	9,310.00	30	🗸 Tagrisso

### ⇒SA2418 Special Authority for Subsidy

**Initial application** — (NSCLC – first line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC); and
  - 2.2 Any of the following:
    - 2.2.1 Patient is treatment naïve; or
    - 2.2.2 Patient has received prior chemotherapy in the adjuvant setting and/or while awaiting EGFR results; or 2.2.3 Both:
      - 2.2.3.1 The patient has discontinued gefitinib or erlotinib due to intolerance; and
      - 2.2.3.2 The cancer did not progress while on gefitinib or erlotinib; and
  - 2.3 There is documentation confirming that the cancer expresses activating mutations of EGFR; and
  - 2.4 Patient has an ECOG performance status 0-3; and
  - 2.5 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (NSCLC – first line) from any relevant practitioner. Approvals valid for 6 months where response to or stable disease with treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.

Initial application — (NSCLC – second line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC); and
  - 2.2 Patient has an ECOG performance status 0-3; and
  - 2.3 The patient must have received previous treatment with erlotinib or gefitinib; and
  - 2.4 There is documentation confirming that the cancer expresses T790M mutation of EGFR following progression on or

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

con	itinu	Jed	١.	

- after erlotinib or gefitinib; and
- 2.5 The treatment must be given as monotherapy; and
- 2.6 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (NSCLC – second line) from any relevant practitioner. Approvals valid for 6 months where response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.

PALBOCICLIB - Special Authority see SA2345 below - Retail pharmacy

Wastage claimable

Tab 75 mg		21	Palbociclib Pfizer
ő	4,000.00		Ibrance
Tab 100 mg		21	Palbociclib Pfizer
C C	4,000.00		<ul> <li>Ibrance</li> </ul>
Tab 125 mg		21	Palbociclib Pfizer
C C	4.000.00		<ul> <li>Ibrance</li> </ul>

(Ibrance Tab 75 mg to be delisted 1 December 2025) (Ibrance Tab 100 mg to be delisted 1 December 2025) (Ibrance Tab 125 mg to be delisted 1 December 2025)

#### ➡SA2345 Special Authority for Subsidy

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

- 1 All of the following:
  - 1.1 Patient has unresectable locally advanced or metastatic breast cancer; and
  - 1.2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
  - 1.3 Patient has an ECOG performance score of 0-2; and

1.4 Either:

1.4.1 Disease has relapsed or progressed during prior endocrine therapy; or

1.4.2 Both:

- 1.4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state; and
- 1.4.2.2 Patient has not received prior systemic treatment for metastatic disease; and
- 1.5 Treatment must be used in combination with an endocrine partner; and
- 1.6 Patient has not received prior funded treatment with a CDK4/6 inhibitor; or
- 2 All of the following:
  - 2.1 Patient has an active Special Authority approval for ribociclib; and
  - 2.2 Patient has experienced a grade 3 or 4 adverse reaction to ribociclib that cannot be managed by dose reductions and requires treatment discontinuation; and
  - 2.3 Treatment must be used in combination with an endocrine partner; and
  - 2.4 There is no evidence of progressive disease since initiation of ribociclib.

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

- 1 Treatment must be used in combination with an endocrine partner; and
- 2 There is no evidence of progressive disease since initiation of palbociclib.

PAZOPANIB - Special Authority see SA2429 on the next page - Retail pharmacy

Brand switch fee payable (Pharmacode 2704692) -	see page 281 for details		
Tab 200 mg	172.88	30	Pazopanib Teva
Tab 400 mg		30	Pazopanib Teva

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

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

### ⇒SA2429 Special Authority for Subsidy

Initial application only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria: Either:

- 1 All of the following:
  - 1.1 The patient has metastatic renal cell carcinoma of predominantly clear cell histology; and
  - 1.2 Either:
    - 1.2.1 The patient is treatment naive; or
    - 1.2.2 The patient has only received prior cytokine treatment; and
  - 1.3 The patient has an ECOG performance score of 0-2; and
    - The patient has intermediate or poor prognosis defined as:
  - 1.4 Any of the following:
    - 1.4.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
    - 1.4.2 Haemoglobin level < lower limit of normal; or
    - 1.4.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
    - 1.4.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
    - 1.4.5 Karnofsky performance score of less than or equal to 70; or
    - 1.4.6 2 or more sites of organ metastasis; and
  - 1.5 Pazopanib to be used for a maximum of 3 months; or

#### 2 All of the following:

- 2.1 The patient has metastatic renal cell carcinoma; and
- 2.2 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
- 2.3 The cancer did not progress whilst on sunitinib; and
- 2.4 Pazopanib to be used for a maximum of 3 months.

**Renewal** only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months where there is no evidence of disease progression.

RIBOCICLIB - Special Authority see SA2495 below - Retail pharmacy

Wastage claimable

Tab 200 mg 1,883.00	21	🗸 Kisqali
3,767.00	42	🗸 Kisqali
5,650.00	63	<ul> <li>Kisqali</li> </ul>

### ⇒SA2495 Special Authority for Subsidy

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

- 1 All of the following:
  - 1.1 Patient has unresectable locally advanced or metastatic breast cancer; and
  - 1.2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
  - 1.3 Patient has an ECOG performance score of 0-2; and
  - 1.4 Either:
    - 1.4.1 Disease has relapsed or progressed during prior endocrine therapy; or
    - 1.4.2 Both:
      - 1.4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state; and
      - 1.4.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease; and
  - 1.5 Treatment to be used in combination with an endocrine partner; and
  - 1.6 Patient has not received prior funded treatment with a CDK4/6 inhibitor; or

Subsidy	Full	/ Brand or
(Manufacturer's Price)	Subsidise	d Generic
\$	Per 🗸	Manufacturer

continued...

- 2 All of the following:
  - 2.1 Patient has an active Special Authority approval for palbociclib; and
  - 2.2 Patient has experienced a grade 3 or 4 adverse reaction to palbociclib that cannot be managed by dose reductions and requires treatment discontinuation; and
  - 2.3 Treatment must be used in combination with an endocrine partner; and
  - 2.4 There is no evidence of progressive disease since initiation of palbociclib.

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

- 1 Treatment must be used in combination with an endocrine partner; and
- 2 There is no evidence of progressive disease since initiation of ribociclib.

RUXOLITINIB - Special Authority see SA1890 below - Retail pharmacy

Wastage claimable

Tab 5 mg2,500.00	56	🖌 Jakavi
Tab 10mg5,000.00	56	🖌 Jakavi
Tab 15 mg	56	🖌 Jakavi
Tab 20 mg5,000.00	56	🖌 Jakavi

#### ➡SA1890 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 The patient has primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis; and
- 2 Either:
  - 2.1 A classification of risk of intermediate-2 or high-risk myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; or
  - 2.2 Both:
    - 2.2.1 A classification of risk of intermediate-1 myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; and
    - 2.2.2 Patient has severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; and
- 3 A maximum dose of 20 mg twice daily is to be given.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 A maximum dose of 20 mg twice daily is to be given.

SUNITINIB - Special Authority see SA2452 below - Retail pharmacy

Cap 12.5 mg	 28	<ul> <li>Sunitinib Pfizer</li> </ul>
Cap 25 mg	 28	<ul> <li>Sunitinib Pfizer</li> </ul>
Cap 50 mg	 28	<ul> <li>Sunitinib Pfizer</li> </ul>

#### ➡SA2452 Special Authority for Subsidy

Initial application — (RCC) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

1 The patient has metastatic renal cell carcinoma; and

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

2 The patient has not previously received funded sunitinib.

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) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

**Renewal** — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: Both:

The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:

- 1 Any of the following:
  - 1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or
  - 1.2 The patient has had a partial response (a decrease in size of 10% or more or decrease in tumour density in Hounsfield Units (HU) of 15% or more on CT and no new lesions and no obvious progression of non measurable disease); or
  - 1.3 The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of 10% or more and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

Renewal — (GIST pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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

TRAMETINIB - Special Authority see SA2496 below - Retail pharmacy

Tab 0.5 mg	2,370.32	30	<ul> <li>Mekinist</li> </ul>
Tab 2 mg	9,481.29	30	🗸 Mekinist

### ⇒SA2496 Special Authority for Subsidy

Initial application — (stage III or IV resected melanoma - adjuvant) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a); or

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

continued...

- 2.1.2 Both:
  - 2.1.2.1 The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor; and 2.1.2.2 Adjuvant treatment with trametinib is required; and
- 2.2 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma; and
- 2.3 Treatment must be adjuvant to complete surgical resection; and
- 2.4 Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and
- 2.5 The individual has a confirmed BRAF mutation; and
- 2.6 Trametinib must be administered in combination with dabrafenib; and
- 2.7 The individual has ECOG performance score 0-2.

#### Notes:

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

Renewal — (stage III or IV resected melanoma - adjuvant) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

- 1 All of the following:
  - 1.1 No evidence of disease recurrence; and
  - 1.2 Trametinib must be administered in combination with dabrafenib; and
  - 1.3 Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadjuvant treatment; or
- 2 All of the following:
  - 2.1 The individual has received adjuvant treatment with a BRAF/MEK inhibitor; and
  - 2.2 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
  - 2.3 The individual meets initial application criteria for trametinib for unresectable or metastatic melanoma; or
- 3 All of the following:
  - 3.1 The individual has received adjuvant treatment with a BRAF/MEK inhibitor; and
  - 3.2 The individual has received a BRAF/MEK inhibitor for unresectable or metastatic melanoma; and
  - 3.3 The individual meets renewal criteria for trametinib for unresectable or metastatic melanoma.

Initial application — (unresectable or metastatic melanoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
  - 2.2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
  - 2.3 The individual has ECOG performance score 0-2; and
  - 2.4 The individual has confirmed BRAF mutation; and
  - 2.5 Trametinib must be administered in combination with dabrafenib; and
  - 2.6 Any of the following:
    - 2.6.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
    - 2.6.2 The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor; or
    - 2.6.3 All of the following:
      - 2.6.3.1 The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor; and

continued...

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist. \*Three months or six months, as applicable, dispensed all-at-once

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

- 2.6.3.2 The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor; and
- 2.6.3.3 The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor.

Renewal — (unresectable or metastatic melanoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 The individual's disease has had a complete response to treatment; or
  - 1.2 The individual's disease has had a partial response to treatment; or
  - 1.3 The individual has stable disease with treatment; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.

## **Endocrine Therapy**

For GnRH ANALOGUES - refer to HORMONE PREPARATIONS, Trophic Hormones, page 89

ABIRATERONE ACETATE – Retail pharmacy-Specialist – Special Authority see SA2118 below Wastage claimable

Tab 250 mg ......4,276.19 120 🗸 Zytiga

## ➡SA2118 Special Authority for Subsidy

Initial application only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has prostate cancer; and
- 2 Patient has metastases; and
- 3 Patient's disease is castration resistant; and
- 4 Either:
  - 4.1 All of the following:
    - 4.1.1 Patient is symptomatic; and
    - 4.1.2 Patient has disease progression (rising serum PSA) after second line anti-androgen therapy; and
    - 4.1.3 Patient has ECOG performance score of 0-1; and
    - 4.1.4 Patient has not had prior treatment with taxane chemotherapy; or
  - 4.2 All of the following:
    - 4.2.1 Patient's disease has progressed following prior chemotherapy containing a taxane; and
    - 4.2.2 Patient has ECOG performance score of 0-2; and
    - 4.2.3 Patient has not had prior treatment with abiraterone.

Renewal — (abiraterone acetate) only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Significant decrease in serum PSA from baseline; and
- 2 No evidence of clinical disease progression; and
- 3 No initiation of taxane chemotherapy with abiraterone; and
- 4 The treatment remains appropriate and the patient is benefiting from treatment.

Renewal - (pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per 🖌	
continued the following criteria: All of the following:			
<ol> <li>The patient is clinically benefiting from treatment and contir</li> <li>Abiraterone acetate to be discontinued at progression; and</li> <li>No initiation of taxane chemotherapy with abiraterone; and</li> <li>The regular Special Authority renewal requirements cannot</li> </ol>			
BICALUTAMIDE Tab 50 mg	4.18	28 🗸	Binarex
FLUTAMIDE			
Tab 250 mg	107.55	90 🗸	Prostacur S29
C C	119.50	100 🗸	Flutamin
FULVESTRANT - Retail pharmacy-Specialist - Special Authority	see SA1895 below		
Inj 50 mg per ml, 5 ml prefilled syringe		2 🖌	Faslodex
SA1895 Special Authority for Subsidy			
<ol> <li>Patient has oestrogen-receptor positive locally advanced of Patient has disease progression following prior treatment w advanced or metastatic disease; and</li> <li>Treatment to be given at a dose of 500 mg monthly followin</li> <li>Treatment to be discontinued at disease progression.</li> <li>Renewal only from a medical oncologist or medical practitioner on for 6 months for applications meeting the following criteria:</li> <li>All of the following:         <ul> <li>Treatment to be given at a dose of 500 mg monthly; and</li> <li>There is no evidence of disease progression.</li> </ul> </li> </ol>	ith an aromatase inf g loading doses; an the recommendatio	nibitor or tamox d	-
OCTREOTIDE Inj 50 mcg per ml, 1 ml vial	27 59	5	Omogo (20)
Inj 50 mcg per ml, 1 ml vial			Omega S29 Omega S29
Inj 500 mcg per ml, 1 ml vial			Omega S29
Inj 50 mcg per ml, 1 ml ampoule			Max Health
			Octreotide GH S29
Inj 100 mcg per ml, 1 ml ampoule			Max Health
, and the second s		<ul> <li>✓</li> </ul>	Octreotide GH S29
		1	Sun Pharma S29
Inj 500 mcg per ml, 1 ml ampoule	113.10	5 🗸	Max Health
		✓	
			Octreotide GH S29
		~	Octreotide GH S29 Sun Pharma S29
		/	
TAMOXIFEN CITRATE ★ Tab 10 mg ★ Tab 20 mg		60 🗸	

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

## Long-acting Somatostatin Analogues

## ⇒SA2445 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 not been successful; and
- 3 Treatment to be given for up to 4 weeks.

Note: Indications marked with \* are unapproved indications.

Renewal — (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 3 months where the treatment remains appropriate and the patient is benefiting from treatment.

**Initial application** — (Acromegaly) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient has acromegaly; and
- 2 Either:
  - 2.1 Treatment with surgery and radiotherapy is not suitable or was unsuccessful; or
  - 2.2 Treatment is for an interim period while awaiting the beneficial effects of radiotherapy; and
- 3 Treatment with a dopamine agonist has been unsuccessful.

Renewal — (Acromegaly) from any relevant practitioner. Approvals valid for 2 years where iGF1 levels have decreased since starting treatment.

Note: In patients with acromegaly, treatment should be discontinued if IGF1 levels have not decreased 3 months after treatment. In patients treated with radiotherapy treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following treatment

withdrawal for at least 4 weeks

**Initial application** — (pre-operative acromegaly) from any relevant practitioner. 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.

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

Any of the following:

- 1 VIPomas and Glucagonomas for patients who are seriously ill in order to improve their clinical state prior to definitive surgery; or
- 2 Both:
  - 2.1 Gastrinoma; and
  - 2.2 Either:
    - 2.2.1 Surgery has been unsuccessful; or
    - 2.2.2 Patient has metastatic disease after treatment with H2 antagonist or proton pump inhibitors has been unsuccessful; or
- 3 Both:
  - 3.1 Insulinomas; and
  - 3.2 Surgery is contraindicated or has not been successful; or

	Subsidy (Manufacturer's Price) \$	Sut Per	Fully osidised	Brand or Generic Manufacturer		
continued						
<ul> <li>For pre-operative control of hypoglycaemia and for maint</li> <li>Both:</li> </ul>	enance therapy; or					
<ul><li>5.1 Carcinoid syndrome (diagnosed by tissue patholo</li><li>5.2 Disabling symptoms not controlled by maximal me</li></ul>		AA analys	sis); and			
Note: The use of a long-acting somatostatin analogue in patient and hypotension will not be funded under Special Authority Renewal — (Other Indications) from any relevant practitioner.		•				
appropriate and the patient is benefiting from treatment.						
ANREOTIDE – Special Authority see SA2445 on the previous Inj 60 mg per 0.5 ml, 0.5 ml syringe		cy 1		lytolac		
nij 60 nig per 0.5 nii, 0.5 nii synnge		I		lytolac S29 S29		
Mytolac to be Principal Supply on 1 August 2025	500.00			A		
Inj 90 mg per 0.5 ml, 0.5 ml syringe Mytolac to be Principal Supply on 1 September 2025		1	• 1	lytolac		
Inj 120 mg per 0.5 ml, 0.5 ml syringe Mytolac to be Principal Supply on 1 August 2025	646.70	1	🗸 N	lytolac		
OCTREOTIDE LONG-ACTING - Special Authority see SA2445		– Retail	•			
Inj depot 10 mg prefiled syringe		1 1	_	andostatin LAR		
Inj depot 20 mg prefilled syringe Inj depot 30 mg prefilled syringe		1		Sandostatin LAR Sandostatin LAR		
Aromatase Inhibitors						
NASTROZOLE						
₭ Tab 1 mg XEMESTANE	4.39	30	✓ <u>µ</u>	Inatrole		
₭ Tab 25 mg ETROZOLE	9.86	30	✓ <u>F</u>	fizer Exemestane		
₭ Tab 2.5 mg	4.36	28	✓ A	ccord S29		
	4.67	30	✓ L	etrole		
Immunosuppressants						
Cytotoxic Immunosuppressants						
AZATHIOPRINE ★ Tab 25 mg	7 36	60		zamun		
* Tab 50 mg		100		zamun		

Mycophenolate powder for oral liquid is subsidised only for patients unable to swallow tablets and capsules, and when the prescription is endorsed accordingly.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Fusion Proteins				
ETANERCEPT - Special Authority see SA2399 below - Retail p	harmacy			
Inj 25 mg		4	🖌 E	Inbrel
Inj 25 mg autoinjector		4	🖌 E	nbrel
Inj 50 mg autoinjector	1,050.00	4	🖌 E	Inbrel
Inj 50 mg prefilled syringe	1,050.00	4	✓ E	Inbrel

## ⇒SA2399 Special Authority for Subsidy

**Initial application** — (adult-onset Still's disease) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 Either:
  - 1.1.1 The patient has had an initial Special Authority approval for adalimumab for adult-onset Still's disease (AOSD); or
  - 1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and

1.2 Either:

- 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or tocilizumab; or
- 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD: or
- 2 All of the following:
  - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
  - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
  - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

**Renewal — (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

## Both:

- 1 Either:
  - 1.1 Applicant is a rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 The patient has a sustained improvement in inflammatory markers and functional status.

Initial application — (ankylosing spondylitis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

## Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and

1.2 Either:

- 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
- 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or
- 2 All of the following:
  - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and
  - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
  - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal

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- anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
- 2.5 Either:
  - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
  - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and
- 2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm

25-34 years - Male: 7.5 cm; Female: 5.5 cm

- 35-44 years Male: 6.5 cm; Female: 4.5 cm
- 45-54 years Male: 6.0 cm; Female: 5.0 cm
- 55-64 years Male: 5.5 cm; Female: 4.0 cm
- 65-74 years Male: 4.0 cm; Female: 4.0 cm

75+ years - Male: 3.0 cm; Female: 2.5 cm

**Renewal** — (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- - 1 Either:
    - 1.1 Applicant is a rheumatologist; or
    - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
  - 2 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
  - 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
  - 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Initial application — (polyarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: Fither:

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:

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist. \*Three months or six months, as applicable, dispensed all-at-once

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- 2.3.1 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 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
  - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA; or
- 2 All of the following:
  - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
  - 2.3 Any of the following:
    - 2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.

Renewal — (oligoarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
  - 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

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**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. Approvals valid for 6 months for applications meeting the following criteria:

- All of the following:
  - 1 Either:
    - 1.1 Applicant is a rheumatologist; or
    - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
  - 2 Either:
    - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
    - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician; and
  - 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

**Initial application — (pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has pyoderma gangrenosum\*; and
- 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
- 3 A maximum of 8 doses.

Note: Indications marked with \* are unapproved indications.

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Renewal — (pyoderma gangrenosum) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment; and
- 3 A maximum of 8 doses.

Initial application — (Arthritis - rheumatoid) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

- Either: 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects; or
    - 1.2.2 The patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis; or
  - 2 All of the following:
    - 2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
    - 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
    - 2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
    - 2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses unless contraindicated); and
    - 2.5 Either:
      - 2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
      - 2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and
    - 2.6 Either:
      - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
      - 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

**Renewal — (Arthritis - rheumatoid)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
  - 2.1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

**Initial application — (severe chronic plaque psoriasis)** only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria: Either:

1 Both:

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- 1.1 The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis; 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 severe chronic plaque psoriasis; or
- 2 All of the following:
  - 2.1 Any of the following:
    - 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; or
    - 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; 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, foot, genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot 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) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Any of the following:

1.1 Both:

- 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
- 1.1.2 Either:
  - 1.1.2.1 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
  - 1.1.2.2 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
- 1.2 Both:
  - 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
  - 1.2.2 Either:
    - 1.2.2.1 Following each prior 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
    - 1.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the

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skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or

- 1.3 Both:
  - 1.3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
  - 1.3.2 Either:
    - 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
    - 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing etanercept; and
- 2 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 Either:
  - 1.1 Applicant is a rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Either:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician; and
- 3 Etanercept to be administered at doses no greater than 50 mg dose every 7 days.

## **Immune Modulators**

ANTITHYMOCYTE GLOBULIN (EQUINE) – PCT only – Specialist			
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BACILLUS CALMETTE-GUERIN (BCG) VACCINE - PCT only - S	Specialist			
Subsidised only for bladder cancer. Inj 2-8 × 100 million CFU	149 37	1	<b>/</b> 0	IncoTICE
Inj 40 mg per ml, vial		3	-	II-Onco-BCG S29
Monoclonal Antibodies				
ADALIMUMAB (AMGEVITA) – Special Authority see SA2400 belo	w – Retail pharmac	y		
Inj 20 mg per 0.4 ml prefilled syringe	190.00	1	🗸 🗸	mgevita
Inj 40 mg per 0.8 ml prefilled pen		2	🗸 🗸	mgevita
Inj 40 mg per 0.8 ml prefilled syringe	375.00	2	✓ Ā	mgevita

## ► SA2400 Special Authority for Subsidy

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

Both:

- 1 The patient has severe Behcet's disease\* that is significantly impacting the patient's quality of life; 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); 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 II 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:

- 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 or any relevant practitioner on the recommendation of 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 plaque 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 Any of the following:
  - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10, where

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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; or
- 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; 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:

Any of the following:

- 1 Both:
  - 1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced a 75% or more reduction in PASI score, 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 experienced 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 experienced reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre treatment baseline value; or
- 3 Both:
  - 3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
  - 3.2 Either:
    - 3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
    - 3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing adalimumab.

**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.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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- 1 Patient has 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.

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) from any relevant practitioner. Approvals valid for 6 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.

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) from any relevant practitioner. 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.

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.

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**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
- 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 Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Initial application — (ankylosing spondylitis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

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- 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 sacroiliitis 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: Either:

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).

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.

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Initial application — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: Either:

1 Both:

- 1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular 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 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
  - 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

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- 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
  - 2.5 Either:
    - 2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
    - 2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and
  - 2.6 Either:
    - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
    - 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

# Renewal — (Arthritis - rheumatoid) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

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: Fither:

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- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and 1.2 Either:
    - 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 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) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has active ulcerative colitis; and
- 2 Either:
  - 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 20; 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:

Either:

- 1 The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on biologic therapy; or
- 2 The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiation on biologic therapy.

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

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

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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 unequivocal sacroiliitis demonstrated by radiological imaging or MRI; 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 experienced a response to at least three months of methotrexate, or azathioprine at a maximum tolerated dose (unless contraindicated); and
- 4 Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated); 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 has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

ADALIMUMAB (HUMIRA - ALTERNATIVE BRAND) - Special Authority see SA2157 below - Retail pharmacy

Inj 20 mg per 0.2 ml prefilled syringe		2	<ul> <li>Humira</li> </ul>
Inj 40 mg per 0.4 ml prefilled pen		2	<ul> <li>HumiraPen</li> </ul>
Inj 40 mg per 0.4 ml prefilled syringe	595.50	2	🗸 Humira

## ➡SA2157 Special Authority for Subsidy

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

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All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Behcet's disease – severe) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The patient has had a good clinical response to treatment with measurably improved quality of life; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (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 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered.

**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. **Initial application — (Psoriasis - severe chronic plaque)** 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 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Psoriasis - severe chronic plaque) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Either:

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- 1.1 Both:
  - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and

1.1.2 Either:

- 1.1.2.1 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
- 1.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or

1.2 Both:

- 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
- 1.2.2 Either:
  - 1.2.2.1 Following each prior 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
  - 1.2.2.2 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
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 A maximum of 8 doses.

**Renewal — (Pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The patient has demonstrated clinical improvement and continues to require treatment; and
- 2 A maximum of 8 doses.

Initial application — (Crohn's disease - adult) 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 Any of the following:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevitat; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

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(Manufacturer's Price)	S	ubsidised	Generic
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3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Crohn's disease - adult) 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 adalimumab; 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 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (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 Any of the following:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; 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: 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 adalimumab; 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 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (Crohn's disease - fistulising) 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 Any of the following:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Crohn's disease - fistulising) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

1 Either:

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(Manufacturer's Price)	Subsidised	I Generic	
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- 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 as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (Ocular inflammation – chronic) from any relevant practitioner. 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 experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- $3\,$  Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Ocular inflammation – chronic) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 The patient has had a good clinical response following 12 weeks' initial treatment; or
  - 1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
  - 1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (Ocular inflammation – severe) from any relevant practitioner. 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 experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Ocular inflammation – severe) 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

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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
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (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 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita); and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**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:

- Both:
  - 1 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
  - 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (Arthritis – oligoarticular course juvenile idiopathic) 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:

All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

Renewal — (Arthritis – oligoarticular course juvenile idiopathic) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months where 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, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

- All of the following:
  - 1 Either:
    - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
    - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
  - 2 Patient has received a maximum of 6 months treatment with Amgevita; and
  - 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

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Renewal — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months where 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 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: All of the following:

1 Either:

- 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
- 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Arthritis - psoriatic) 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 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
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application** — (Arthritis – rheumatoid) 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 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication, 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 — (Arthritis – rheumatoid)** 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 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
- 2 Either:
  - 2.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
  - 2.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Initial application — (Still's disease – adult-onset (AOSD)) 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:

▲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	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

Renewal — (Still's disease – adult-onset (AOSD)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has demonstrated a sustained improvement in inflammatory markers and functional status.

AFLIBERCEPT – Special Authority see SA1772 below – Retail pharmacy

Inj 40 mg per ml, 0.1 ml vial...... 1,250.00 1 🖌 Eylea

## ⇒SA1772 Special Authority for Subsidy

Initial application — (wet age related macular degeneration) only from an ophthalmologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 Any of the following:
    - 1.1.1 Wet age-related macular degeneration (wet AMD); or
    - 1.1.2 Polypoidal choroidal vasculopathy; or
    - 1.1.3 Choroidal neovascular membrane from causes other than wet AMD; and
  - 1.2 Either:
    - 1.2.1 The patient has developed severe endophthalmitis or severe posterior uveitis following treatment with bevacizumab; or
    - 1.2.2 There is worsening of vision or failure of retina to dry despite three intraocular injections of bevacizumab four weeks apart; and
  - 1.3 There is no structural damage to the central fovea of the treated eye; and
  - 1.4 Patient has not previously been treated with ranibizumab for longer than 3 months; or
- 2 Either:
  - 2.1 Patient has current approval to use ranibizumab for treatment of wAMD and was found to be intolerant to ranibizumab within 3 months; or
  - 2.2 Patient has previously\* (\*before June 2018) received treatment with ranibizumab for wAMD and disease was stable while on treatment.

Initial application — (diabetic macular oedema) only from an ophthalmologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has centre involving diabetic macular oedema (DMO); and
- 2 Patient's disease is non responsive to 4 doses of intravitreal bevacizumab when administered 4-6 weekly; and
- 3 Patient has reduced visual acuity between 6/9 6/36 with functional awareness of reduction in vision; and
- 4 Patient has DMO within central OCT (ocular coherence tomography) subfield > 350 micrometers; and
- 5 There is no centre-involving sub-retinal fibrosis or foveal atrophy.

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

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

continued...

3 There is no structural damage to the central fovea of the treated eye.

Renewal — (diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 There is stability or two lines of Snellen visual acuity gain; and
- 2 There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid); and
- 3 Patient's vision is 6/36 or better on the Snellen visual acuity score; and
- 4 There is no centre-involving sub-retinal fibrosis or foveal atrophy; and
- 5 After each consecutive 12 months treatment with (2nd line anti-VEGF agent), patient has retrialled with at least one injection of bevacizumab and had no response.

BENRALIZUMAB - Special Authority see SA2151 on the next page - Retail pharmacy

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

## ⇒SA2151 Special Authority for Subsidy

**Initial application** — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
- 3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
- 4 Patient has a blood eosinophil count of greater than 0.5 × 10<sup>9</sup> cells/L in the last 12 months; and
- 5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long-acting beta-2 agonist, or budesonide/formoterol as part of the anti-inflammatory reliever therapy plus maintenance regimen, unless contraindicated or not tolerated; and
- 6 Either:
  - 6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
  - 6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
- 7 Treatment is not to be used in combination with subsidised mepolizumab; and
- 8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and

9 Either:

- 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or 9.2 Both:
  - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
  - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

- Both:
  - 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and

2 Either:

- 2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with benralizumab; or
- 2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

BEVACIZUMAB - PCT only - Special Authority see SA2453 below

Inj 25 mg per ml, 4 ml vial	69.00	1 🖌	Vegzelma
Inj 25 mg per ml, 16 ml vial2	76.00	1 🖌	Vegzelma
Inj 1 mg for ECP	0.71 1	mg 🗸	Baxter

## ➡SA2453 Special Authority for Subsidy

**Initial application** — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Patient is currently on treatment with bevacizumab, and met all remaining criteria prior to commencing treatment; or

- 2 All of the following:
  - 2.1 Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and

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

continued...

- 2.2 Patient has preserved liver function (Child-Pugh A); and
- 2.3 Transarterial chemoembolisation (TACE) is unsuitable; and
- 2.4 Any of the following:
  - 2.4.1 Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
  - 2.4.2 Patient received funded lenvatinib before 1 March 2025; or
  - 2.4.3 Both:
    - 2.4.3.1 Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
    - 2.4.3.2 No disease progression since initiation of lenvatinib; and
- 2.5 Patient has an ECOG performance status of 0-2; and
- 2.6 To be given in combination with atezolizumab.

Renewal — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

Initial application — (advanced or metastatic ovarian cancer) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 The patient has FIGO Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; or
  - 1.2 Both:
    - 1.2.1 The patient has previously untreated advanced (FIGO Stage IIIB or IIIC) epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
    - 1.2.2 Either:
      - 1.2.2.1 Debulking surgery is inappropriate; or
      - 1.2.2.2 The cancer is sub-optimally debulked (maximum diameter of any gross residual disease greater than 1cm); and
- 2 Bevacizumab to be administered at a maximum dose of 15 mg/kg every three weeks; and
- 3 18 weeks concurrent treatment with chemotherapy is planned.

Renewal — (advanced or metastatic ovarian cancer) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

Initial application — (Recurrent Respiratory Papillomatosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Maximum of 6 doses; and
- 2 The patient has recurrent respiratory papillomatosis; and
- 3 The treatment is for intra-lesional administration.

Renewal — (Recurrent Respiratory Papillomatosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Maximum of 6 doses; and
- 2 The treatment is for intra-lesional administration; and
- 3 There has been a reduction in surgical treatments or disease regrowth as a result of treatment.

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

Either:

- 1 Ocular neovascularisation; or
- 2 Exudative ocular angiopathy.

## BRENTUXIMAB VEDOTIN - PCT only - Special Authority see SA2289 on the next page

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	nufacturer's Price)	Subsid	ised	Generic
	\$	Per	1	Manufacturer

## ➡SA2289 Special Authority for Subsidy

**Initial application — (relapsed/refractory Hodgkin lymphoma)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Both:
    - 1.1.1 Patient has relapsed/refractory CD30-positive Hodgkin lymphoma after two or more lines of chemotherapy; and
    - 1.1.2 Patient is ineligible for autologous stem cell transplant; or
  - 1.2 Both:
    - 1.2.1 Patient has relapsed/refractory CD30-positive Hodgkin lymphoma; and
    - 1.2.2 Patient has previously undergone autologous stem cell transplant; and
- 2 Patient has not previously received funded brentuximab vedotin; and
- 3 Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
- 4 Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Renewal — (relapsed/refractory Hodgkin lymphoma) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
- 2 Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and 3 Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment.

**Initial application** — (anaplastic large cell lymphoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has relapsed/refractory CD30-positive systemic anaplastic large cell lymphoma; and
- 2 Patient has an ECOG performance status of 0-1; and
- 3 Patient has not previously received brentuximab vedotin; and
- 4 Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
- 5 Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Renewal — (anaplastic large cell lymphoma) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

С

- 1 Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
- 2 Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and
- 3 Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment.

CETUXIMAB - PCT only - Specialist - Special Authority s	ee SA2401 below		
Inj 5 mg per ml, 20 ml vial		1	<ul> <li>Erbitux</li> </ul>
Inj 5 mg per ml, 100 ml vial	1,820.00	1	<ul> <li>Erbitux</li> </ul>
Inj 1 mg for ECP	3.82	1 mg	<ul> <li>Baxter</li> </ul>

#### ➡SA2401 Special Authority for Subsidy

**Initial application** — (head and neck cancer, locally advanced) only from a relevant specialist or any relevant 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, non-metastatic, squamous cell cancer of the head and neck; and
- 2 Cisplatin is contraindicated or has resulted in intolerable side effects; and
- 3 Patient has an ECOG performance score of 0-2; and

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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4 To be administered in combination with radiation therapy.

**Initial application** — (colorectal cancer, metastatic) only from a relevant specialist or any relevant 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 colorectal cancer located on the left side of the colon (see Note); and
- 2 There is documentation confirming disease is RAS and BRAF wild-type; and
- 3 Patient has an ECOG performance score of 0-2; and
- 4 Patient has not received prior funded treatment with cetuximab; and
- 5 Either:
  - 5.1 Cetuximab is to be used in combination with chemotherapy; or
    - 5.2 Chemotherapy is determined to not be in the best interest of the patient based on clinician assessment.

Renewal — (colorectal cancer, metastatic) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where there is no evidence of disease progression.

Note: Left-sided colorectal cancer comprises of the distal one-third of the transverse colon, the splenic flexure, the descending colon, the sigmoid colon, or the rectum.

Inj 5 mg vial	 	73.00	1	Mylotarg

## ⇒SA2269 Special Authority for Subsidy

Initial application only from a haematologist, paediatric haematologist or paediatric oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has not received prior chemotherapy for this condition; and
- 2 Patient has de novo CD33-positive acute myeloid leukaemia; and
- 3 Patient does not have acute promyelocytic leukaemia; and
- 4 Gemtuzumab ozogamicin will be used in combination with standard anthracycline and cytarabine (AraC); and
- 5 Patient is being treated with curative intent; and
- 6 Patient's disease risk has been assessed by cytogenetic testing to be good or intermediate; and
- 7 Patient must be considered eligible for standard intensive remission induction chemotherapy with standard anthracycline and cytarabine (AraC); and
- 8 Gemtuzumab ozogamicin to be funded for one course only (one dose at 3 mg per m<sup>2</sup> body surface area or up to 2 vials of 5 mg as separate doses).

Note: Acute myeloid leukaemia excludes acute promyelocytic leukaemia and acute myeloid leukaemia that is secondary to another haematological disorder (eg myelodysplasia or myeloproliferative disorder).

INFLIXIMAB - PCT only - Special Authority see SA2487 below

Inj 100 mg		1	Remicade
Inj 1 mg for ECP	4.40	1 mg	<ul> <li>Baxter</li> </ul>

#### ➡SA2487 Special Authority for Subsidy

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

All of the following:

- 1 Patient has 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

Subsidy	F	ully	Brand or	
(Manufacturer's Price)	Subsidi	sed	Generic	
\$	Per	✓	Manufacturer	

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- 2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Patient has tried but has experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease (adults)) from any relevant practitioner. Approvals valid for 2 years 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, or HBI score has reduced by 3 points, from when the patient was initiated on infliximab; or
  - 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
  - 1.3 The patient has demonstrated an adequate response to treatment but CDAI score and/or HBI 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)) from any relevant practitioner. Approvals valid for 6 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 experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease (children)) from any relevant practitioner. Approvals valid for 2 years 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 fulminant ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks for applications meeting the following criteria: Both:

- 1 Patient has acute, fulminant ulcerative colitis; and
- 2 Treatment with intravenous or high dose oral corticosteroids has not been successful.

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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 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) 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
- 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.

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

Both:

- 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 Patent has complex peri-anal fistula.

Renewal — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Either:
  - 1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
  - 1.2 There has been a marked reduction in drainage of all fistula(e) from baseline (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (neurosarcoidosis) only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months for applications meeting the following criteria: All of the following:

- 1 Patient has been diagnosed with 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:

Either:

- 1 A withdrawal period has been tried and the patient has relapsed; or
- 2 All of the following:
  - 2.1 A withdrawal period has been considered but would not be clinically appropriate; and
  - 2.2 There has been a marked reduction in prednisone dose; and
  - 2.3 Either:
    - 2.3.1 There has been an improvement in MRI appearances; or
    - 2.3.2 Marked improvement in other symptomology.

Initial application — (plaque psoriasis) only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 3 months for applications meeting the following criteria: Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis; and
- 1.2 Either:
  - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab; or

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- 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 Any of the following:
    - 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; or
    - 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; 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, foot, genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot 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) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 Both:
    - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
    - 1.1.2 Following each prior infliximab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab treatment baseline value; or
  - 1.2 Both:
    - 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
    - 1.2.2 Either:
      - 1.2.2.1 Following each prior infliximab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
      - 1.2.2.2 Following each prior infliximab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab treatment baseline value; or

1.3 Both:

- 1.3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
- 1.3.2 Either:

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- 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
- 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

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

Both:

- 1 Patient was being treated with infliximab prior to 1 February 2019; and
- 2 Any of the following:
  - 2.1 Rheumatoid arthritis; or
  - 2.2 Ankylosing spondylitis; or
  - 2.3 Psoriatic arthritis; or
  - 2.4 Severe ocular inflammation; or
  - 2.5 Chronic ocular inflammation; or
  - 2.6 Crohn's disease (adults); or
  - 2.7 Crohn's disease (children); or
  - 2.8 Fistulising Crohn's disease; or
  - 2.9 Severe fulminant ulcerative colitis; or
  - 2.10 Severe ulcerative colitis; or
  - 2.11 Plaque psoriasis; or
  - 2.12 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

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- 2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept; and
- 3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.

**Renewal** — (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2 Either:

- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 3 Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks.

Initial application — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes); and
- 2 Either:
  - 2.1 The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes); or
  - 2.2 The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes); and
- 3 The patient is experiencing significant loss of quality of life.

Notes: Behcet's disease diagnosed according to the International Study Group for Behcet's Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7.

Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.

Renewal — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Renewal — (fulminant ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years 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

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meeting the following criteria:

Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe ocular inflammation; or

2 Both:

- 2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
- 2.2 Any of the following:
  - 2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
  - 2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
  - 2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

Renewal — (severe ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses; or
- 2 Following each 12 month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

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

All of the following:

- 1 Patient has active ulcerative colitis; and
- 2 Either:
  - 2.1 Patients SCCAI is greater than or equal to 4; or
  - 2.2 Patients PUCAI score is greater than or equal to 20; and
- 3 Patient has tried but has experienced an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

1 Either:

- 1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab; or
- 1.2 The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on infliximab; 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

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considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

**Initial application — (pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has pyoderma gangrenosum\*; and
- 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g.
- prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
- 3 A maximum of 8 doses.

Note: Note: Indications marked with \* are unapproved indications.

Renewal — (pyoderma gangrenosum) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment; and
- 3 A maximum of 8 doses.

Initial application — (inflammatory bowel arthritis – axial) from any relevant practitioner. 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 had axial inflammatory pain for six months or more; and
- 3 Patient is unable to take NSAIDs; and
- 4 Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI; and
- 5 Patient's disease has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
- 6 Patient has 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) from any relevant practitioner. 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 experienced a response to at least three months of methotrexate or azathioprine at a maximum tolerated dose (unless contraindicated); and
- 4 Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated); 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.

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**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 experienced 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 has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

Initial application — (immune checkpoint inhibitor toxicity in malignancy\*) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy; and
- 2 The individual has received insufficient benefit from use of corticosteroids; and
- 3 Infliximab is to be administered at up to 5mg/kg for up to four doses.

Renewal — (immune checkpoint inhibitor toxicity in malignancy\*) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The individual has shown clinical improvement and ongoing treatment is required; and
- 2 Infliximab is to be administered at up to 5mg/kg for up to a total of 8 doses.

Note: Indications marked with \* are unapproved indications.

INOTUZUMAB OZOGAMICIN - PCT only - Specialist - Special Authority see SA2460 below

Inj 1 mg vial	 1	<ul> <li>Besponsa</li> </ul>
Inj 1 mg for ECP	 1 mg	<ul> <li>Baxter</li> </ul>

### ► SA2460 Special Authority for Subsidy

Initial application only from a relevant specialist or any relevant 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 relapsed or refractory CD22-positive B-cell acute lymphoblastic leukaemia/lymphoma, including minimal residual disease; and
- 2 Patient has ECOG performance status of 0-2; and
- 3 Either:
  - 3.1 Both:
    - 3.1.1 Patient has Philadelphia chromosome positive B-Cell ALL; and
    - 3.1.2 Patient has previously received a tyrosine kinase inhibitor; or
  - 3.2 Patient has received one prior line of treatment involving intensive chemotherapy; and
- 4 Treatment is to be administered for a maximum of 3 cycles.

**Renewal** only from a relevant specialist or any relevant 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 is not proceeding to a stem cell transplant; and

2 Either:

- 2.1 Patient has experienced complete disease response; or
- 2.2 Patient has experienced complete remission with incomplete haematological recovery; and
- 3 Treatment with inotuzumab ozogamicin is to cease after a total duration of 6 cycles.
- MEPOLIZUMAB Special Authority see SA2331 on the next page Retail pharmacy

Inj 100 mg prefilled pen		Nucala
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### ⇒SA2331 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  $0.5 \times 10^{\circ}9$  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 Treatment is not to be used in combination with subsidised benralizumab; and
  - 8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
  - 9 Either:
    - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or 9.2 Both:
      - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
      - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

- Both:
  - 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
  - 2 Either:
    - 2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with mepolizumab; or
    - 2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

**Initial application** — (eosinophilic granulomatosis with polyangiitis) only from a relevant specialist or any relevant 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 eosinophilic granulomatosis with polyangiitis; and
- 2 The patient has trialled and not received adequate benefit from at least one of the following for at least three months (unless contraindicated to all): azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate, or rituximab; and
- 3 Either:
  - 3.1 The patient has trialled prednisone for a minimum of three months and is unable to maintain disease control at

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist. \*Three months or six months, as applicable, dispensed all-at-once

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doses below 7.5 mg per day; or

3.2 Corticosteroids are contraindicated.

Renewal — (eosinophilic granulomatosis with polyangiitis) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where patient has no evidence of clinical disease progression.

OBINUTUZUMAB - PCT only - Specialist - Special Author	ity see SA2155 below		
Inj 25 mg per ml, 40 ml vial		1	🖌 Gazyva
Inj 1 mg for ECP	6.21	1 mg	<ul> <li>Baxter</li> </ul>

### ⇒SA2155 Special Authority for Subsidy

**Initial application** — (chronic lymphocytic leukaemia) only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is obinutuzumab treatment naive; and
- 3 The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min); and
- 4 Patient has adequate neutrophil and platelet counts\* unless the cytopenias are a consequence of marrow infiltration by CLL; and
- 5 Patient has good performance status; and
- 6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

Notes: Chronic lymphocytic leukaemia includes small lymphocytic lymphoma. Comorbidity refers only to illness/impairment other than CLL induced illness/impairment in the patient. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with obinutuzumab is expected to improve symptoms and improve ECOG score to < 2.

\* Neutrophil greater than or equal to  $1.5 \times 10^9$ /L and platelets greater than or equal to  $75 \times 10^9$ /L.

Initial application — (follicular / marginal zone lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria: All of the following:

1 Either:

- 1.1 Patient has follicular lymphoma; or
- 1.2 Patient has marginal zone lymphoma; and
- 2 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen\*; and
- 3 Patient has an ECOG performance status of 0-2; and
- 4 Patient has been previously treated with no more than four chemotherapy regimens; and
- 5 Obinutuzumab to be administered at a maximum dose of 1000 mg for a maximum of 6 cycles in combination with chemotherapy\*.
- Note: \* includes unapproved indications

**Renewal — (follicular / marginal zone lymphoma)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria: All of the following:

- 1 Patient has no evidence of disease progression following obinutuzumab induction therapy; and
- 2 Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years; and
- 3 Obinutuzumab to be discontinued at disease progression.

OMALIZUMAB - Special Authority see SA1744 on the ne	xt page - Retail pharmacy		
Inj 150 mg prefilled syringe		1	<ul> <li>Xolair</li> </ul>
			🗸 Xolair AU
Inj 150 mg vial		1	<ul> <li>Xolair</li> </ul>

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

### ⇒SA1744 Special Authority for Subsidy

**Initial application** — (severe asthma) only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 6 years or older; and
- 2 Patient has a diagnosis of severe asthma; and
- 3 Past or current evidence of atopy, documented by skin prick testing or RAST; and
- 4 Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
- 5 Proven adherence with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1,600 mcg per day or fluticasone propionate 1,000 mcg per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 mcg bd or eformoterol 12 mcg bd) for at least 12 months, unless contraindicated or not tolerated; and
- 6 Either:
  - 6.1 Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated; or
  - 6.2 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral steroids; and
- 7 Patient has an Asthma Control Test (ACT) score of 10 or less; and
- 8 Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 26 weeks after the first dose to assess response to treatment.

**Initial application — (severe chronic spontaneous urticaria)** only from a clinical immunologist or dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above; and
    - 2.1.2 Patient has a Dermatology life quality index (DLQI) of 10 or greater; or
  - 2.2 Patient has a Urticaria Control Test (UCT) of 8 or less; and
- 3 Any of the following:
  - 3.1 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (> 3 mg/kg day) for at least 6 weeks; or
  - 3.2 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months; or
  - 3.3 Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin; and
- 4 Either:
  - 4.1 Treatment to be stopped if inadequate response\* following 4 doses; or
  - 4.2 Complete response\* to 6 doses of omalizumab.

Renewal — (severe asthma) only from a clinical immunologist or respiratory specialist. Approvals valid for 2 years for applications meeting the following criteria:

#### Both:

1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and

2 A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline.

Renewal — (severe chronic spontaneous urticaria) only from a clinical immunologist or dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Patient has previously adequately responded\* to 6 doses of omalizumab; or

2 Both:

▲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		Fully	Brand or	
(Manufacturer's Price)	Subsi	dised	Generic	
\$	Per	1	Manufacturer	

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- 2.1 Patient has previously had a complete response\* to 6 doses of omalizumab; and
- 2.2 Patient has relapsed after cessation of omalizumab therapy.

Note: \*Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

PALIVIZUMAB - PCT only - Special Authority see SA2419 below

Inj 100 mg per ml, 1 ml vial...... 1,700.00 1 🖌 Synagis

### ➡SA2419 Special Authority for Subsidy

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

- 1 Palivizumab to be administered during the annual RSV season; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Infant was born in the last 12 months; and
    - 2.1.2 Infant was born at less than 32 weeks zero days' gestation; or
  - 2.2 Both:
    - 2.2.1 Child was born in the last 24 months; and
    - 2.2.2 Any of the following:
      - 2.2.2.1 Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community; or
      - 2.2.2.2 Both:
        - 2.2.2.2.1 Child has haemodynamically significant heart disease; and
        - 2.2.2.2.2 Any of the following:
          - 2.2.2.2.1 Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B); or
          - 2.2.2.2.2.2 Child has unoperated or surgically palliated complex congenital heart disease; or
          - 2.2.2.2.3 Child has severe pulmonary hypertension (see Note C); or
          - 2.2.2.2.2.4 Child has moderate or severe left ventricular (LV) failure (see Note D); or
      - 2.2.2.3 Child has severe combined immune deficiency, confirmed by an immunologist, but has not received a stem cell transplant; or
      - 2.2.2.4 Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist.

**Renewal** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Palivizumab to be administered during the annual RSV season; and
- 2 Child was born in the last 24 months; and
- 3 Any of the following:
  - 3.1 Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community; or
  - 3.2 Both:
    - 3.2.1 Child has haemodynamically significant heart disease; and
    - 3.2.2 Any of the following:
      - 3.2.2.1 Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B); or
      - 3.2.2.2 Child has unoperated or surgically palliated complex congenital heart disease; or

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continued				
3.2.2.3 Child has severe pulmonary hyperter 3.2.2.4 Child has moderate or severe left ver			); or	
3.3 Child has severe combined immune deficiency, co transplant; or	,	0 /		
3.4 Child has inborn errors of immunity (see Note E) th infections, confirmed by an immunologist.	nat increase susceptil	oility to life-	threate	ening viral respiratory
Notes:				
<ul> <li>Ventilatory/respiratory support includes those on home ox managed at home</li> </ul>				
<ul> <li>b) Child requires/will require heart failure medication, and/or require surgical palliation/definitive repair within the next 3</li> <li>c) Mean pulmonary artery pressure more than 25 mmHg</li> <li>d) LV Ejection Fraction less than 40%</li> </ul>	child has significant p months	oulmonary	hyperte	ension, and/or infant will
e) Inborn errors of immunity include, but are not limited to, IF	NAR deficiencies			
PERTUZUMAB – PCT only – Specialist – Special Authority see Inj 30 mg per ml, 14 ml vial	3,927.00	1		erjeta
Inj 420 mg for ECP	3,927.00 420	0 mg OP	✓ E	laxter
SA2276 Special Authority for Subsidy Initial application — (metastatic breast cancer) from any relevent meeting the following criteria: All of the following:	vant practitioner. App	orovals vali	d for 1	2 months for applications
<ol> <li>The patient has metastatic breast cancer expressing HER and</li> <li>Either:</li> </ol>	-2 IHC 3+ or ISH+ (ir	ncluding FIS	SH or o	other current technology);
<ul><li>2.1 Patient is chemotherapy treatment naïve; or</li><li>2.2 Patient has not received prior treatment for their m</li><li>12 months between prior (neo)adjuvant chemother</li></ul>				
<ul> <li>3 The patient has good performance status (ECOG grade 0</li> <li>4 Pertuzumab to be administered in combination with trastu</li> <li>5 Pertuzumab maximum first dose of 840 mg, followed by m</li> </ul>	zumab; and	very 3 wee	eks; an	d
6 Pertuzumab to be discontinued at disease progression.				
Renewal — (metastatic breast cancer) from any relevant pract the following criteria: Either:	itioner. Approvals va	alid for 12 n	nonths	for applications meeting
1 Both:				
<ol> <li>1.1 The patient has metastatic breast cancer expressin technology); and</li> </ol>	ng HER-2 IHC 3+ or I	SH+ (inclu	ding Fl	SH or other current
<ol> <li>The cancer has not progressed at any time point d trastuzumab; or</li> </ol>	uring the previous 12	months w	hilst or	pertuzumab and
2 All of the following:				
0.4 Definition and involve discontinue by the second				

- 2.1 Patient has previously discontinued treatment with pertuzumab and trastuzumab 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 pertuzumab and trastuzumab.

RITUXIMAB (MABTHERA) - PCT only - Specialist - Spe	cial Authority see SA1976	6 on the nex	t page
Inj 100 mg per 10 ml vial	1,075.50	2	<ul> <li>Mabthera</li> </ul>
Inj 500 mg per 50 ml vial	2,688.30	1	<ul> <li>Mabthera</li> </ul>
Inj 1 mg for ECP	5.64	1 mg	🗸 Baxter (Mabthera)

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

### ⇒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 Either:
  - 6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
  - 6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 7 Either:
  - 7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and
- 8 Either:
  - 8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and 9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Initial application — (rheumatoid arthritis - prior TNF inhibitor use) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Both:
  - 1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
    - 1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
  - 2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  - 2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Renewal — (rheumatoid arthritis - re-treatment in 'partial responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

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

#### continued...

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.

Inj 100 mg per 10 ml vial		Riximyo
Inj 500 mg per 50 ml vial		Riximyo
Inj 1 mg for ECP	1.38 1 mg	<ul> <li>Baxter (Riximyo)</li> </ul>

### ► SA2497 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/m<sup>2</sup> 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

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist. \*Three months or six months, as applicable, dispensed all-at-once

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

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- 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/m<sup>2</sup> 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 and rituximab treatment is to be used in combination with funded venetoclax; and
- 3 The patient has good performance status; and
- 4 Either:
  - 4.1 The patient does not have chromosome 17p deletion CLL; or
  - 4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
- 5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and
- 6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2. **Renewal — (Chronic lymphocytic leukaemia)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

Sub	bsidy F	ully	Brand or
(Manufactu	urer's Price) Subsidi	sed	Generic
	\$ Per	✓	Manufacturer

continued...

- 1 Either:
  - 1.1 The patient's disease has relapsed and rituximab treatment is to be used in combination with funded venetoclax; or 1.2 All of the following:
    - 1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
    - 1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and
    - 1.2.3 The patient does not have chromosome 17p deletion CLL; and
    - 1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and
- 2 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles.

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

Initial application — (Neuromyelitis Optica Spectrum Disorder(NMOSD)) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks; and
- 2 Either:
  - 2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or
  - 2.2 All of the following:
    - 2.2.1 The patient has experienced a breakthrough attack of NMOSD; and
    - 2.2.2 The patient is receiving treatment with mycophenolate; and
    - 2.2.3 The 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
- 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.

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AThree 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		Fully	Brand or	
(Manufacturer's Pr	rice) Sut	bsidised	Generic	
\$	Per	1	Manufacturer	

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Initial application — (Severe Refractory Myasthenia Gravis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years for applications meeting the following criteria: Both:

- 1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- 2 Either:
  - 2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or
  - 2.2 Both:
    - 2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
    - 2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Renewal — (Severe Refractory Myasthenia Gravis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Either:
  - 3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or
  - 3.2 Both:
    - 3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and
    - 3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Initial application — (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient is a child with SDNS\* or FRNS\*; and
- 2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
- 3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
- 4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
- 5 The total rituximab dose used would not exceed the equivalent of 375 mg/m<sup>2</sup> 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/m<sup>2</sup> of body surface area per week for a total of 4 weeks.

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Note: Indications marked with \* are unapproved indications.

Initial application — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria: All of the following:

- 1 Patient is a child with SRNS\* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and
- 2 Treatment with tacrolimus for at least 3 months has been ineffective; and
- 3 Genetic causes of nephrotic syndrome have been excluded; and
- 4 The total rituximab dose used would not exceed the equivalent of 375 mg/m<sup>2</sup> 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/m<sup>2</sup> of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Initial application — (aggressive CD20 positive NHL) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has treatment naive aggressive CD20 positive NHL; and
  - 1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
  - 1.3 To be used for a maximum of 8 treatment cycles; or
- 2 Both:
  - 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
  - 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

Renewal — (aggressive CD20 positive NHL) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
- 3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
- 4 To be used for a maximum of 4 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

Initial application — (haemophilia with inhibitors) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

- 1 Patient has mild congenital haemophilia complicated by inhibitors; or
- 2 Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy; or
- 3 Patient has acquired haemophilia.

**Renewal** — (haemophilia with inhibitors) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:

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All of the following:

- 1 Patient was previously treated with rituximab for haemophilia with inhibitors; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment.

**Initial application — (immune thrombocytopenic purpura (ITP))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: All of the following:

1 Either:

- 1.1 Patient has immune thrombocytopenic purpura\* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
- 1.2 Patient has immune thrombocytopenic purpura\* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
- 2 Any of the following:
  - 2.1 Treatment with steroids and splenectomy have been ineffective; or
  - 2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
  - 2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy); and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Renewal — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: Either:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m<sup>2</sup> weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura\*; and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

Initial application — (indolent, low-grade lymphomas or hairy cell leukaemia\*) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

Either:

- 1 Both:
  - 1.1 The patient has indolent low grade NHL or hairy cell leukaemia\* with relapsed disease following prior chemotherapy; and
  - 1.2 To be used for a maximum of 6 treatment cycles; or

2 Both:

- 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia\* requiring first-line systemic chemotherapy; and
- 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. \*Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Renewal — (indolent, low-grade lymphomas or hairy cell leukaemia\*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 The patient has had a rituximab treatment-free interval of 12 months or more; and

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- 2 The patient has indolent, low-grade NHL or hairy cell leukaemia\* with relapsed disease following prior chemotherapy; and
- 3 To be used for no more than 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. \*Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant. Initial application — (pure red cell aplasia (PRCA)) only from a haematologist or Practitioner on the recommendation of a

haematologist. Approvals valid for 6 weeks where patient has autoimmune pure red cell aplasia\* associated with a demonstrable B-cell lymphoproliferative disorder.

Note: Indications marked with \* are unapproved indications.

Renewal — (pure red cell aplasia (PRCA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient was previously treated with rituximab for pure red cell aplasia\* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months.

Note: Indications marked with \* are unapproved indications.

**Initial application** — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: All of the following:

- 1 Patient has cold haemagglutinin disease\*; and
- 2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Renewal — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: Either:

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

Note: Indications marked with \* are unapproved indications.

**Initial application** — (thrombotic thrombocytopenic purpura (TTP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: Both:

- 1 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks; and
- 2 Either:
  - 2.1 Patient has thrombotic thrombocytopenic purpura\* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or

2.2 Patient has acute idiopathic thrombotic thrombocytopenic purpura\* with neurological or cardiovascular pathology. Note: Indications marked with \* are unapproved indications.

Renewal — (thrombotic thrombocytopenic purpura (TTP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: All of the following:

- 1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura\*; and
- 2 An initial response lasting at least 12 months was demonstrated; and

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- 3 Patient now requires repeat treatment; and
- 4 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.
- Note: Indications marked with \* are unapproved indications.

Initial application — (treatment refractory systemic lupus erythematosus (SLE)) only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 7 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe, immediately life- or organ-threatening SLE\*; and
- 2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and
- 3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and
- 4 Maximum of four 1000 mg infusions of rituximab.
- Note: Indications marked with \* are unapproved indications.

Renewal — (treatment refractory systemic lupus erythematosus (SLE)) only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient's SLE\* achieved at least a partial response to the previous round of prior rituximab treatment; and
- 2 The disease has subsequently relapsed; and
- 3 Maximum of two 1000 mg infusions of rituximab.

Note: Indications marked with \* are unapproved indications.

**Initial application** — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: All of the following:

- 1 Patient has warm autoimmune haemolytic anaemia\*; and
- 2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

**Renewal** — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: Either:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m<sup>2</sup> weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia\*; and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

- 1 Patient has confirmed antisynthetase syndrome; and
- 2 Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and

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- 3 Either:
  - 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 × 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/m<sup>2</sup> of body surface area per week for a total of 4 weeks.

**Initial application** — (severe chronic inflammatory demyelinating polyneuropathy) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD); and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
    - 2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
  - 2.2 Rapid treatment is required due to life threatening complications; and
- 3 One of the following dose regimens is to be used: 375 mg/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 Either:
  - 2.1 Both:

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

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

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- 2.1.1 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 Roth

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

2 Both:

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

Renewal — (CD20+ low grade or follicular B-cell NHL) from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria:

Both:

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

**Initial application** — (Membranous nephropathy) only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 6 weeks for applications meeting the following criteria: All of the following:

1 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:

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- 2.1 Treatment with rituximab was previously successful, but the condition has relapsed, and the patient now requires repeat treatment; or
- 2.2 Patient achieved partial response to treatment and requires repeat treatment (see Note); and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Notes:

- a) Indications marked with \* are unapproved indications.
- b) High risk of progression to end-stage kidney disease defined as > 5g/day proteinuria.
- c) Conservative measures include renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents unless contraindicated or the patient has experienced intolerable side effects.
- d) Partial response defined as a reduction of proteinuria of at least 50% from baseline, and between 0.3 grams and 3.5 grams per 24 hours.

Initial application — (B-cell acute lymphoblastic leukaemia/lymphoma\*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient has newly diagnosed B-cell acute lymphoblastic leukaemia/lymphoma\*; and
- 2 Treatment must be in combination with an intensive chemotherapy protocol with curative intent; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/m<sup>2</sup> 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.

**Initial application** — (pemiphigus\*) only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 Patient has severe rapidly progressive pemphigus; and
  - 1.2 Is used in combination with systemic corticosteroids (20 mg/day); and
  - 1.3 Any of the following:
    - 1.3.1 Skin involvement is at least 5% body surface area; or
    - 1.3.2 Significant mucosal involvement (10 or more mucosal erosions) or diffuse gingivitis or confluent large erosions; or
    - 1.3.3 Involvement of two or more mucosal sites; or
- 2 Both:
  - 2.1 Patient has pemphigus; and
  - 2.2 Patient has not experienced adequate clinical benefit from systemic corticosteroids (20 mg/day) in combination with a steroid sparing agent, unless contraindicated.

Note: Indications marked with \* are unapproved indications.

Renewal — (pemiphigus\*) only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Patient has experienced adequate clinical benefit from rituximab treatment, with improvement in symptoms and healing of

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skin ulceration and reduction in corticosteroid requirement; and

2 Patient has not received rituximab in the previous 6 months.

Note: Indications marked with \* are unapproved indications.

Initial application — (immunoglobulin G4-related disease (IgG4-RD\*)) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed diagnosis of IgG4-RD\*; and
- 2 Either:
  - 2.1 Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs for at least 3 months has been ineffective in lowering corticosteroid dose below 5 mg per day (prednisone equivalent) without relapse; or
  - 2.2 Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance; and

3 Total rituximab dose used should not exceed a maximum of two 1000 mg infusions of rituximab given two weeks apart. Note: Indications marked with \* are unapproved indications.

Renewal — (immunoglobulin G4-related disease (IgG4-RD\*)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Treatment with rituximab for IgG4-RD\* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed; or
  - 1.2 Patient is receiving maintenance treatment for IgG4-RD\*; and
- 2 Rituximab re-treatment not to be given within 6 months of previous course of treatment; and
- 3 Maximum of two 1000 mg infusions of rituximab given two weeks apart.
- Note: Indications marked with \* are unapproved indications.

SECUKINUMAB - Special Authority see SA2488 below - Retail pharmacy

<ul> <li>Cosentyx</li> </ul>	1	ge799.50	I, 1 ml prefilled syringe	Inj 150 mg per ml,
<ul> <li>Cosentyx</li> </ul>	2	1,599.00		

### SA2488 Special Authority for Subsidy

**Initial application** — (severe chronic plaque psoriasis – second-line biologic) only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a Health NZ Hospital, for severe chronic plaque psoriasis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
  - 2.2 The patient has received insufficient benefit from adalimumab, etanercept or infliximab; and
- 3 A Psoriasis Area and Severity Index (PASI) assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

**Initial application** — (severe chronic plaque psoriasis – first-line biologic) only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

1 Any of the following:

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- 1.1 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; or
- 1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; 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. foot, genital or flexural areas, at least 2 of the 3 PASI symptom sub scores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot 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) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Both:

1 Fither

- 1.1 Either:
  - 1.1.1 Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab; or
  - 1.1.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; or

1.2 Both:

- 1.2.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
- 1.2.2 Either:
  - 1.2.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
  - 1.2.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and
- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

**Initial application** — (ankylosing spondylitis – second-line biologic) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months for applications meeting the following criteria: Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

Renewal - (ankylosing spondylitis - second-line biologic) only from a rheumatologist or medical practitioner on the

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

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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 300 mg monthly.

Initial application — (psoriatic arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis; and
  - 1.2 Either:
    - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
    - 1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or infliximab to meet the renewal criteria for adalimumab, etanercept or infliximab for psoriatic arthritis; or
- 2 All of the following:
  - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
  - 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
  - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
  - 2.4 Either:
    - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
    - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  - 2.5 Any of the following:
    - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
    - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
    - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

**Renewal — (psoriatic arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

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- 1 Either:
  - 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior secukinumab treatment in the opinion of the treating physician; and
- 2 Secukinumab to be administered at doses no greater than 300 mg monthly.

SILTUXIMAB - Special Authority see SA1596 on the next page - Retail pharmacy

Note: Siltuximab is to be administered at doses no greate	er than 11 mg/kg every	/ 3 weeks.	
Inj 100 mg vial	770.57	1	<ul> <li>Sylvant</li> </ul>
Inj 400 mg vial		1	<ul> <li>Sylvant</li> </ul>

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

### ⇒SA1596 Special Authority for Subsidy

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

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Renewal only from a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status.

TOCILIZUMAB - PCT only - Special Authority see SA2489 below

Ini 20 mg per ml. 10 ml vial	
Inj 20 mg per ml, 10 ml vial	а
Inj 20 mg per ml, 20 ml vial	а
Inj 1 mg for ECP	

#### ➡SA2489 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 Both:
  - 1.1 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
  - 1.2 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 ENABLE trial programme; and
  - 2.2 The patient has developed CRS or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following 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 or ICANS for CAR T-cell therapy at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

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

Both:

- 1 Patient was being treated with tocilizumab prior to 1 February 2019; and
- 2 Any of the following:
  - 2.1 rheumatoid arthritis; or
  - 2.2 systemic juvenile idiopathic arthritis; or
  - 2.3 adult-onset Still's disease; or
  - 2.4 polyarticular juvenile idiopathic arthritis; or
  - 2.5 idiopathic multicentric Castleman's disease.

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or

	Subsidy	Fi	illy	Brand or
(Manu	facturer's Price)	Subsidis	ed	Generic
	\$ F	Per	~	Manufacturer

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- 2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
- 3 Either:
  - 3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or 3.2 Both;
    - 3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital; and 3.2.2 Either:
      - 3.2.2.1 The patient has experienced intolerable side effects from rituximab; or
      - 3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

**Initial application** — (Rheumatoid Arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
- 2 Tocilizumab is to be used as monotherapy; and
- 3 Either:
  - 3.1 Treatment with methotrexate is contraindicated; or
  - 3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
- 4 Either:
  - 4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent; or
  - 4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and
- 5 Either:
  - 5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints; or
  - 5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 6 Either:
  - 6.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 6.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

**Initial application — (systemic juvenile idiopathic arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

- Both:
  - 1 Patient diagnosed with systemic juvenile idiopathic arthritis; and
  - 2 Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotrexate; non-steroidal anti-inflammatory drugs (NSAIDs); and systemic corticosteroids.

**Initial application — (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

- Either:
  - 1 Both:
    - 1.1 Either:
      - 1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD); or

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

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- 1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD; or
- 2 All of the following:
  - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
  - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate; and
  - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initial application — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: Fither:

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.

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.

**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:

 Subsidy (Manufacturer's Price)	Fi	ully sed	Brand or Generic	
\$	Per	1	Manufacturer	

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- 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: Fither:

- 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 Either:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
  - 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Renewal — (idiopathic multicentric Castleman's disease) only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status.

Initial application — (immune checkpoint inhibitor toxicity in malignancy\*) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy; and
- 2 The individual has received insufficient benefit from use of corticosteroids; and
- 3 Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly.

**Renewal — (immune checkpoint inhibitor toxicity in malignancy\*)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The individual has shown clinical improvement and ongoing treatment is required; and
- 2 Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly.

Note: Indications marked with \* are unapproved indications.

TRASTUZUMAB (HERZUMA) – PCT only – Special Authority see SA2293 below

Inj 150 mg vial	1	🗸 Herzuma
Inj 440 mg vial	1	✓ Herzuma
Inj 1 mg for ECP0.70	1 mg	✓ Baxter

### ⇒SA2293 Special Authority for Subsidy

Initial application — (early breast cancer) from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

Both:

Subsidy		Fully	Brand or	
(Manufacturer's Price)	5	Subsidised	Generic	
\$	Per	1	Manufacturer	

continued...

- 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).

Renewal — (early breast cancer\*) 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 metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
  - 1.2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
  - 1.3 Any of the following:
    - 1.3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
    - 1.3.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; or
    - 1.3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and

1.4 Either:

- 1.4.1 Trastuzumab will not be given in combination with pertuzumab; or
- 1.4.2 All of the following:
  - 1.4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
  - 1.4.2.2 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
  - 1.4.2.3 The patient has good performance status (ECOG grade 0-1); and
- 1.5 Trastuzumab to be discontinued at disease progression; or
- 2 All of the following:
  - 2.1 Patient has previously discontinued treatment with trastuzumab in the metastatic setting 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 trastuzumab.

Note: \* For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer

Initial application — (metastatic breast cancer) from any relevant practitioner. 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 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; and
- 3 Either:
  - 3.1 Trastuzumab will not be given in combination with pertuzumab; or
  - 3.2 All of the following:
    - 3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
    - 3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
    - 3.2.3 The patient has good performance status (ECOG grade 0-1); and

Subsidy		Fully	Brand or
(Manufacturer's Price)	5	Subsidised	Generic
\$	Per	1	Manufacturer

continued...

4 Trastuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) 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 metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
  - 1.2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
  - 1.3 Trastuzumab to be discontinued at disease progression; or

2 All of the following:

- 2.1 Patient has previously discontinued treatment with trastuzumab 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 trastuzumab.

Initial application - (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner.

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

- 1 The patient has locally advanced or metastatic gastric, gastro-oesophageal junction or oesophageal cancer expressing HER-2 IHC 2+ FISH+ or IHC3+ (or other current technology); and
- 2 Patient has an ECOG score of 0-2.

Renewal — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 2 Trastuzumab to be discontinued at disease progression.

TRASTUZUMAB DERUXTECAN - PCT only - Specia	I Authority see SA2420 below		
Inj 100 mg per ml, 1 ml vial	2,550.00	1	🗸 Enhertu
Inj 1 mg for ECP		1 mg	<ul> <li>Baxter</li> </ul>

### ► SA2420 Special Authority for Subsidy

Initial application only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with trastuzumab deruxtecan and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has metastatic breast cancer expressing HER-2 IHC3+ or ISH+ (including FISH or other current technology); and
  - 2.2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
  - 2.3 Either:
    - 2.3.1 The patient has received prior therapy for metastatic disease; or
    - 2.3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy; and
  - 2.4 Patient has a good performance status (ECOG 0-1); and
  - 2.5 Patient has not received prior funded trastuzumab deruxtecan treatment; and
  - 2.6 Treatment to be discontinued at disease progression.

**Renewal** only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

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

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Both:

- 1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab deruxtecan; and
- 2 Treatment to be discontinued at disease progression.
- Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

TRASTUZUMAB EMTANSINE - PCT only - Specialisi	- Special Authority see SA24	24 below	
Inj 100 mg vial	2,320.00	1	🗸 Kadcyla
Inj 160 mg vial		1	🗸 Kadcyla
Inj 1 mg for ECP	24.52	1 mg	<ul> <li>Baxter</li> </ul>

### ► SA2424 Special Authority for Subsidy

Initial application — (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has early breast cancer expressing HER2 IHC3+ or ISH+; and
- 2 Documentation of pathological invasive residual disease in the breast and/or axiliary lymph nodes following completion of surgery; and
- 3 Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery; and
- 4 Disease has not progressed during neoadjuvant therapy; and
- 5 Patient has left ventricular ejection fraction of 45% or greater; and
- 6 Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery; and
- 7 Trastuzumab emtansine to be discontinued at disease progression; and
- 8 Total adjuvant treatment duration must not exceed 42 weeks (14 cycles).

**Initial application** — (metastatic breast cancer) only from a relevant specialist or any relevant 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 Either:
  - 6.1 Patient has not received prior funded trastuzumab emtansine or trastuzumab deruxtecan treatment; or
  - 6.2 Both:
    - 6.2.1 Patient has discontinued trastuzumab deruxtecan due to intolerance; and
    - 6.2.2 The cancer did not progress while on trastuzumab deruxtecan; and
- 7 Treatment to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
- 2 Treatment to be discontinued at disease progression.

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

USTEKINUMAB - Special Authority see SA2182 on the next page - Retail pharmacy

Inj 90 mg per ml, 1 ml pre-filled syringe......4,162.00 1 Stelara

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

### ⇒SA2182 Special Authority for Subsidy

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

Either:

- 1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
- 2 Both:
  - 2.1 Patient has active Crohn's disease; and
  - 2.2 Either:
    - 2.2.1 Patient has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      - 2.2.2.2 Other biologics for Crohn's disease are contraindicated.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy; or
  - 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
  - 1.3 The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and
- 2 Ustekinumab to be administered at a dose no greater than 90 mg every 8 weeks.

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

Either:

- 1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
- 2 Both:
  - 2.1 Patient has active Crohn's disease; and
  - 2.2 Either:
    - 2.2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      - 2.2.2.2 Other biologics for Crohn's disease are contraindicated.

Note: Indication marked with \* is an unapproved indication.

Renewal — (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
  - 1.2 PCDAI score is 15 or less; or
  - 1.3 The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed; and
- 2 Ustekinumab to administered at a dose no greater than 90 mg every 8 weeks.
- Note: Indication marked with \* is an unapproved indication.

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

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

Either:

- 1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
- 2 Both:
  - 2.1 Patient has active ulcerative colitis; and
  - 2.2 Either:
    - 2.2.1 Patient has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for ulcerative colitis; and
      - 2.2.2.2 Other biologics for ulcerative colitis are contraindicated.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

1 Either:

- 1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy; or
- 1.2 PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy\*; and
- 2 Ustekinumab will be used at a dose no greater than 90 mg intravenously every 8 weeks.

Note: Criterion marked with \* is for an unapproved indication.

VEDOLIZUMAB - PCT only - Special Authority see SA2183 below

### ⇒SA2183 Special Authority for Subsidy

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

All of the following:

- 1 Patient has active Crohn's disease; and
- 2 Any of the following:
  - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
  - 2.2 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
  - 2.3 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  - 2.4 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
  - 2.5 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Any of the following:
  - 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
  - 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
  - 3.3 Immunomodulators and corticosteroids are contraindicated.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated

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- on biologic therapy; or
- 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
- 1.3 The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and
- 2 Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.

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

### All of the following:

- 1 Paediatric patient has active Crohn's disease; and
- 2 Any of the following:
  - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
  - 2.2 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
  - 2.3 Patient has extensive small intestine disease; and
- 3 Any of the following:
  - 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
  - 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
  - 3.3 Immunomodulators and corticosteroids are contraindicated.

Note: Indication marked with \* is an unapproved indication.

Renewal — (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
  - 1.2 PCDAI score is 15 or less; or
  - 1.3 The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed; and
- 2 Vedolizumab to administered at a dose no greater than 300mg every 8 weeks.

Note: Indication marked with \* is an unapproved indication.

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

All of the following:

- 1 Patient has active ulcerative colitis; and
- 2 Any of the following:
  - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
  - 2.2 Patient has a SCCAI score is greater than or equal to 4; or
  - 2.3 Patient's PUCAI score is greater than or equal to  $20^*$ ; and
- 3 Any of the following:
  - 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
  - 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
  - 3.3 Immunomodulators and corticosteroids are contraindicated.

Note: Indication marked with \* is an unapproved indication.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

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(Manufacturer's Price)	Subsidised	Generic
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1 Either:

- 1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy; or
- 1.2 The PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy \*; and
- 2 Vedolizumab will be used at a dose no greater than 300 mg intravenously every 8 weeks.

Note: Indication marked with \* is an unapproved indication.

### Programmed Cell Death-1 (PD-1) Inhibitors

ATEZOLIZUMAB - PCT only - Specialist - Special Autho	rity see SA2443 below		
Inj 60 mg per ml, 20 ml vial		1	<ul> <li>Tecentriq</li> </ul>
Inj 1 mg for ECP	8.08	1 mg	<ul> <li>Baxter</li> </ul>

### ➡SA2443 Special Authority for Subsidy

**Initial application** — (non-small cell lung cancer second line monotherapy) only from a medical oncologist or any relevant 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 locally advanced or metastatic non-small cell lung cancer; and
- 2 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 3 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 4 Patient has an ECOG 0-2; and
- 5 Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
- 6 Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
- 7 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (non-small cell lung cancer second line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
- 3 No evidence of disease progression; and
- 4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
- 5 Atezolizumab to be used at a maximum dose of 1200 mg every three weeks (or equivalent); and
- 6 Treatment with atezolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

**Initial application** — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

- Either:
  - 1 Patient is currently on treatment with atezolizumab and met all remaining criteria prior to commencing treatment; or
  - 2 All of the following:
    - 2.1 Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and
    - 2.2 Patient has preserved liver function (Child-Pugh A); and

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

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- 2.3 Transarterial chemoembolisation (TACE) is unsuitable; and
- 2.4 Any of the following:
  - 2.4.1 Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
  - 2.4.2 Patient received funded lenvatinib before 1 March 2025; or
  - 2.4.3 Both:
    - 2.4.3.1 Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
    - 2.4.3.2 No disease progression since initiation of lenvatinib; and
- 2.5 Patient has an ECOG performance status of 0-2; and
- 2.6 To be given in combination with bevacizumab.

Renewal — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

DURVALUMAB - PCT only - Specialist - Special Authority see SA24	25 below		
Inj 50 mg per ml, 10 ml vial4	,700.00	1	🖌 Imfinzi
Inj 50 mg per ml, 2.4 ml vial1	,128.00	1	🖌 Imfinzi
Inj 1 mg for ECP		1 mg	<ul> <li>Baxter</li> </ul>

### ► SA2425 Special Authority for Subsidy

**Initial application** — (Non-small cell lung cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Either:
  - Patient has histologically or cytologically documented stage III, locally advanced, unresectable non-small cell lung cancer (NSCLC); or
  - 1.2 Patient has histologically or cytologically documented stage IIb (T1N2a only), locally advanced, unresectable non-small cell lung cancer (NSCLC); and
- 2 Patient has received two or more cycles of platinum-based chemotherapy concurrently with definitive radiation therapy; and
- 3 Patient has no disease progression following the second or subsequent cycle of platinum-based chemotherapy with definitive radiation therapy treatment; and
- 4 Patient has a ECOG performance status of 0 or 1; and
- 5 Patient has completed last radiation dose within 8 weeks of starting treatment with durvalumab; and
- 6 Patient must not have received prior PD-1 or PD-L1 inhibitor therapy for this condition; and
- 7 Either:
  - 7.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
  - 7.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
- 8 Treatment with durvalumab to cease upon signs of disease progression.

**Renewal** — (Non-small cell lung cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

1 The treatment remains clinically appropriate and the patient is benefitting from treatment; and

- 2 Either:
  - 2.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
  - 2.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
- 3 Treatment with durvalumab to cease upon signs of disease progression; and
- 4 Total continuous treatment duration must not exceed 12 months.

IPILIMUMAB – PCT only – Specialist – Special Authority	y see SA2461 on the next page
Inj 5 mg per ml, 10 ml vial	

Inj 5 mg per ml, 40 ml vial	 1	<ul> <li>Yervoy</li> </ul>
Inj 1 mg for ECP	 1 mg	<ul> <li>Baxter</li> </ul>

Yervov

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	\$	Per	✓	Manufacturer

### ➡SA2461 Special Authority for Subsidy

**Initial application** — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient is currently on treatment with ipilimumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The patient has metastatic renal cell carcinoma; and
  - 2.2 The patient is treatment naive; and
  - 2.3 The patient has ECOG performance status 0-2; and
  - 2.4 The disease is predominantly of clear cell histology; and
  - 2.5 Any of the following:
    - 2.5.1 The patient has sarcomatoid histology; or
    - 2.5.2 Haemoglobin levels less than the lower limit of normal; or
    - 2.5.3 Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L); or
    - 2.5.4 Neutrophils greater than the upper limit of normal; or
    - 2.5.5 Platelets greater than the upper limit of normal; or
    - 2.5.6 Interval of less than 1 year from original diagnosis to the start of systemic therapy; or
    - 2.5.7 Karnofsky performance score of less than or equal to 70; and

2.6 Ipilimumab is to be used at a maximum dose of 1 mg/kg for up to four cycles in combination with nivolumab..

NIVOLUMAB - PCT only - Specialist - Special Authority see SA2490 below

Inj 10 mg per ml, 4 ml vial1,051.9	98 1	<ul> <li>Opdivo</li> </ul>
Inj 10 mg per ml, 10 ml vial2,629.9	96 1	<ul> <li>Opdivo</li> </ul>
Inj 1 mg for ECP27.2	22 1 mg	<ul> <li>Baxter</li> </ul>

#### ⇒SA2490 Special Authority for Subsidy

**Initial application** — (unresectable or metastatic melanoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The individual has ECOG performance 0-2; and
- 4 Either:
  - 4.1 The individual has not received funded pembrolizumab; or
  - 4.2 Both:
    - 4.2.1 The individual 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 indvidual was on pembrolizumab; and
- 5 Any of the following:
  - 5.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
  - 5.2 The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; or
  - 5.3 All of the following:
    - 5.3.1 The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; and
    - 5.3.2 The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor; and
    - 5.3.3 The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor.

Renewal — (unresectable or metastatic melanoma, less than 24 months on treatment) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

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(Manufacturer's Price)	S	Subsidised	Generic
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1 Both:

- 1.1 Any of the following:
  - 1.1.1 The individual's disease has had a complete response to treatment; or
  - 1.1.2 The individual's disease has had a partial response to treatment; or
  - 1.1.3 The individual has stable disease; and
- 1.2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; or
- 2 All of the following:
  - 2.1 The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
  - 2.2 The individual has signs of disease progression; and
  - 2.3 Disease has not progressed during previous treatment with nivolumab.

Renewal — (unresectable or metastatic melanoma, more than 24 months on treatment) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The individual has been on treatment for more than 24 months; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Any of the following:
      - 2.1.1.1 The individual's disease has had a complete response to treatment; or
      - 2.1.1.2 The individual's disease has had a partial response to treatment; or
      - 2.1.1.3 The individual has stable disease; and
    - 2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; or
  - 2.2 All of the following:
    - 2.2.1 The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
    - 2.2.2 The individual has signs of disease progression; and
    - 2.2.3 Disease has not progressed during previous treatment with nivolumab.

# **Initial application — (renal cell carcinoma, first line)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

#### Either:

- 1 Patient is currently on treatment with nivolumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The patient has metastatic renal cell carcinoma; and
  - 2.2 The patient is treatment naive; and
  - 2.3 The patient has ECOG performance status 0-2; and
  - 2.4 The disease is predominantly of clear cell histology; and
  - 2.5 Any of the following:
    - 2.5.1 The patient has sarcomatoid histology; or
    - 2.5.2 Haemoglobin levels less than the lower limit of normal; or
    - 2.5.3 Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L); or
    - 2.5.4 Neutrophils greater than the upper limit of normal; or
    - 2.5.5 Platelets greater than the upper limit of normal; or
    - 2.5.6 Interval of less than 1 year from original diagnosis to the start of systemic therapy; or
    - 2.5.7 Karnofsky performance score of less than or equal to 70; and

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- 2.6 Nivolumab is to be used in combination with ipilimumab for the first four treatment cycles at a maximum dose of 3 mg/kg; and
- 2.7 Nivolumab is to be used as monotherapy at a maximum maintenance dose of 240 mg every 2 weeks (or equivalent).

# **Initial application** — (Renal cell carcinoma, second line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic renal-cell carcinoma; and
- 2 The disease is of predominant clear-cell histology; and
- 3 Patient has ECOG performance status 0-2; and
- 4 Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy; and
- 5 Patient has not previously received a funded immune checkpoint inhibitor; and
- 6 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

Renewal — (Renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

PEMBROLIZUMAB - PCT only - Specialist - Special Authority see SA2498 below

Inj 25 mg per ml, 4 ml vial	4,680.00 1	🗸 Keytruda
Inj 1 mg for ECP		<ul> <li>Baxter</li> </ul>

#### ⇒SA2498 Special Authority for Subsidy

**Initial application** — (stage III or IV resectable melanoma - neoadjuvant) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note); and
  - 2.2 The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma; and
  - 2.3 Treatment must be prior to complete surgical resection; and
  - 2.4 Pembrolizumab must be administered as monotherapy; and
  - 2.5 The individual has ECOG performance score 0-2; and
  - 2.6 Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent).

Renewal — (stage III or IV resectable melanoma - neoadjuvant) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Any of the following:

1 Both:

Subsidy	Fully	Brand or	
(Manufacturer's Price)	Subsidised	Generic	
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- 1.1 The individual has received neoadjuvant treatment with an immune checkpoint inhibitor; and
- 1.2 The individual meets initial application criteria for pembrolizumab for stage III or IV resected melanoma adjuvant;
- 2 Both:
  - 2.1 The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor; and
  - 2.2 The individual meets renewal criteria for pembrolizumab for stage III or IV resected melanoma adjuvant; or
- 3 All of the following:

0

- 3.1 The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor; and
- 3.2 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 3.3 The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma; or

#### 4 All of the following:

- 4.1 The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor; and
- 4.2 The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma; and
- 4.3 The individual meets renewal criteria for pembrolizumab for unresectable or metastatic melanoma.

#### Notes:

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means either 13 weeks after resection (primary or lymphadenectomy) or 13 weeks prior to the scheduled date of the resection (primary or lymphadenectomy)

Initial application — (stage III or IV resected melanoma - adjuvant) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 The individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a); and
  - 2.2 Adjuvant treatment with pembrolizumab is required; and
  - 2.3 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma; and
  - 2.4 Treatment must be in addition to complete surgical resection; and
  - 2.5 Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and
  - 2.6 Pembrolizumab must be administered as monotherapy; and
  - 2.7 The individual has ECOG performance score 0-2; and
  - 2.8 Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent).

#### Notes:

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

Renewal — (stage III or IV resected melanoma - adjuvant) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Any of the following:

- 1 All of the following:
  - 1.1 No evidence of disease recurrence; and
  - 1.2 Pembrolizumab must be administered as monotherapy; and
  - 1.3 Pembrolizumab to be administered at a fixed dose of 200 mg every three weeks (or equivalent) for a maximum of 12 months total treatment course, including any systemic neoadjuvant treatment; and

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(Manufacturer's Price)	Subsidised	Generic
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- 1.4 Treatment to be discontinued at signs of disease recurrence or at completion of 12 months total treatment course (equivalent to 18 cycles at a dose of 200 mg every 3 weeks), including any systemic neoadjuvant treatment; or
- 2 All of the following:
  - 2.1 The individual has received adjuvant treatment with an immune checkpoint inhibitor; and
  - 2.2 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
  - 2.3 The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma; or
- 3 All of the following:
  - 3.1 The individual has received adjuvant treatment with an immune checkpoint inhibitor; and
  - 3.2 The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma; and
  - 3.3 The individual meets renewal criteria for pembrolizumab for unresectable or metastatic melanoma.

**Initial application** — (unresectable or metastatic melanoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The individual has ECOG performance score of 0-2; and
- 4 Either:
  - 4.1 The individual has not received funded nivolumab; or
  - 4.2 Both:
    - 4.2.1 The individual 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 individual was on nivolumab; and
- 5 Any of the following:
  - 5.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
  - 5.2 The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; or
  - 5.3 All of the following:
    - 5.3.1 The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; and
    - 5.3.2 The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor; and
    - 5.3.3 The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor.

Renewal — (unresectable or metastatic melanoma, less than 24 months on treatment) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Both:
  - 1.1 Any of the following:
    - 1.1.1 The individual's disease has had a complete response to treatment; or
    - 1.1.2 The individual's disease has had a partial response to treatment; or
    - 1.1.3 The individual has stable disease; and
  - 1.2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; or
- 2 All of the following:
  - 2.1 The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
  - 2.2 The individual has signs of disease progression; and
  - 2.3 Disease has not progressed during previous treatment with pembrolizumab.

▲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		Fully	Brand or	
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Renewal — (unresectable or metastatic melanoma, more than 24 months on treatment) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The individual has been on treatment for more than 24 months; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Any of the following:
      - 2.1.1.1 The individual's disease has had a complete response to treatment; or
      - 2.1.1.2 The individual's disease has had a partial response to treatment; or
      - 2.1.1.3 The individual has stable disease; and
    - 2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; or
  - 2.2 All of the following:
    - 2.2.1 The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
    - 2.2.2 The individual has signs of disease progression; and
    - 2.2.3 Disease has not progressed during previous treatment with pembrolizumab.

**Initial application** — (non-small cell lung cancer first-line monotherapy) only from a medical oncologist or any relevant 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 locally advanced or metastatic, unresectable, non-small cell lung cancer; and
- 2 Patient has not had chemotherapy for their disease in the palliative setting; and
- 3 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 4 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 5 Pembrolizumab to be used as monotherapy; and
- 6 Either:
  - 6.1 There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain; or
  - 6.2 Both:
    - 6.2.1 There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain; and
    - 6.2.2 Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and
- 7 Patient has an ECOG 0-2; and
- 8 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
- 9 Baseline measurement of overall tumour burden is documented clinically and radiologically.

**Renewal — (non-small cell lung cancer first line monotherapy)** only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
- 3 No evidence of disease progression; and
- 4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
- 5 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 6 Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

**Initial application — (non-small cell lung cancer first-line combination therapy)** only from a medical oncologist or any relevant 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 locally advanced or metastatic, unresectable, non-small cell lung cancer; and
- 2 The patient has not had chemotherapy for their disease in the palliative setting; and
- 3 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 4 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 5 Pembrolizumab to be used in combination with platinum-based chemotherapy; and
- 6 Patient has an ECOG 0-2; and
- 7 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
- 8 Baseline measurement of overall tumour burden is documented clinically and radiologically.

**Renewal — (non-small cell lung cancer first line combination therapy)** only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
- 3 No evidence of disease progression; and
- 4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
- 5 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 6 Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

**Initial application** — (breast cancer, advanced) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 Patient has recurrent or de novo unresectable, inoperable locally advanced triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]); or
    - 2.1.2 Patient has recurrent or de novo metastatic triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]); and
  - 2.2 Patient is treated with palliative intent; and

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▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist. \*Three months or six months, as applicable, dispensed all-at-once

Subsidy		Fully	Brand or
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- 2.3 Patient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10; and
- 2.4 Patient has received no prior systemic therapy in the palliative setting; and
- 2.5 Patient has an ECOG score of 0-2; and
- 2.6 Pembrolizumab is to be used in combination with chemotherapy; and
- 2.7 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 2.8 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (breast cancer, advanced) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Response to treatment in target lesions has been determined by a comparable radiologic assessment following the most recent treatment period; and
- 4 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 5 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

**Initial application** — (head and neck squamous cell carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has recurrent or metastatic head and neck squamous cell carcinoma of mucosal origin (excluding nasopharyngeal carcinoma) that is incurable by local therapies; and
  - 2.2 Patient has not received prior systemic therapy in the recurrent or metastatic setting; and
  - 2.3 Patient has a positive PD-L1 combined positive score (CPS) of greater than or equal to 1; and
  - 2.4 Patient has an ECOG performance score of 0-2; and
  - 2.5 Either:
    - 2.5.1 Pembrolizumab to be used in combination with platinum-based chemotherapy; or
    - 2.5.2 Pembrolizumab to be used as monotherapy; and
  - 2.6 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (head and neck squamous cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 4 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application - (MSI-H/dMMR advanced colorectal cancer) only from a relevant specialist or any relevant practitioner on

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the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer; or
    - 2.1.2 Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer; and
  - 2.2 Individual is treated with palliative intent; and
  - 2.3 Individual has not previously received funded treatment with pembrolizumab for MSI-H/dMMR advanced colorectal cancer; and
  - 2.4 Individual has an ECOG performance score of 0-2; and
  - 2.5 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
  - 2.6 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (MSI-H/dMMR advanced colorectal cancer) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 No evidence of disease progression; and
- 2 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 3 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (Urothelial carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has inoperable locally advanced (T4) or metastatic urothelial carcinoma; and
  - 2.2 Patient has an ECOG performance score of 0-2; and
  - 2.3 Patient has documented disease progression following treatment with chemotherapy; and
  - 2.4 Pembrolizumab to be used as monotherapy at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (Urothelial carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 4 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

**Initial application** — (relapsed/refractory Hodgkin lymphoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

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- 1 Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 Both:
      - 2.1.1.1 Individual has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy; and
      - 2.1.1.2 Individual is ineligible for autologous stem cell transplant; or
    - 2.1.2 Individual has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant; and
  - 2.2 Individual has not previously received funded pembrolizumab for relapsed/refractory Hodgkin lymphoma; and
  - 2.3 Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks.

Renewal — (relapsed/refractory Hodgkin lymphoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 Patient has received a partial or complete response to pembrolizumab; and
- 2 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

### Other Immunosuppressants

#### CICLOSPORIN

Cap 25 mg Cap 50 mg Cap 100 mg		50 50 50	<ul> <li>✓ Neoral</li> <li>✓ Neoral</li> <li>✓ Neoral</li> </ul>
Oral liq 100 mg per ml		50 ml OP	<ul> <li>Neoral</li> </ul>
EVEROLIMUS – Special Authority see SA2414 below – I Wastage claimable	Retail pharmacy		
Tab 10 mg	6,512.29	30	<ul> <li>Afinitor</li> </ul>
Tab 5 mg	4,555.76	30	<ul> <li>Afinitor</li> </ul>

#### ⇒SA2414 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.

Initial application — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has metastatic renal cell carcinoma; and
  - 1.2 The disease is of predominant clear-cell histology; and
  - 1.3 The patient has documented disease progression following one previous line of treatment; and

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	\$ Per	1	Manufacturer

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- 1.4 The patient has an ECOG performance status of 0-2; and
- 1.5 Everolimus is to be used in combination with lenvatinib; or
- 2 All of the following:
  - 2.1 Patient has received funded treatment with nivolumab for the second line treatment of metastatic renal cell carcinoma; and
  - 2.2 Patient has experienced treatment limiting toxicity from treatment with nivolumab; and
  - 2.3 Everolimus is to be used in combination with lenvatinib; and
  - 2.4 There is no evidence of disease progression.

Renewal — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

SIROLIMUS	- Special Authority se	e SA2270 below -	- Retail pharmacy
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Tab 1 mg		100	<ul> <li>Rapamune</li> </ul>
Tab 2 mg	1,499.99	100	<ul> <li>Rapamune</li> </ul>
Oral liq 1 mg per ml		60 ml OP	<ul> <li>Rapamune</li> </ul>

### ⇒SA2270 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

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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
- 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: Those of childbearing age potential are not required to trial phenytoin sodium, sodium valproate, or topiramate. Those who can father children are not required to trial 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 SA2455 on the n	ext page – Retail pharmad	cy	
Cap 0.5 mg		100	<ul> <li>Tacrolimus Sandoz</li> </ul>
Cap 0.75 mg		100	<ul> <li>Tacrolimus Sandoz</li> </ul>
Cap 1 mg		100	<ul> <li>Tacrolimus Sandoz</li> </ul>
Cap 5 mg	248.20	50	<ul> <li>Tacrolimus Sandoz</li> </ul>

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### ⇒SA2455 Special Authority for Subsidy

**Initial application — (organ transplant)** only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The individual is an organ transplant recipient; or
- 2 The individual is receiving induction therapy for an organ transplant.

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 Either:

- 2.1 Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response; or
- 2.2 Patient is a child with nephrotic syndrome\*.

Note: Indications marked with \* are unapproved indications

### **JAK** inhibitors

UPADACITINIB - Special Authority see SA2483 below - Retail	l pharmacy		
Tab modified-release 15 mg		28	🗸 Rinvoq
Tab modified-release 30 mg	2,033.00	28	<ul> <li>Rinvoq</li> </ul>
Tab modified-release 45 mg	3,049.00	28	<ul> <li>Rinvoq</li> </ul>

#### ⇒SA2483 Special Authority for Subsidy

Initial application — (Rheumatoid Arthritis (previously treated with adalimumab or etanercept)) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

- All of the following:
  - 1 The individual has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
  - 2 Either:
    - 2.1 The individual has experienced intolerable side effects with adalimumab and/or etanercept; or
    - 2.2 The individual 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 Any of the following:
    - 3.1 Rituximab is not clinically appropriate; or
    - 3.2 The individual is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or 3.3 Both:
      - 3.3.1 The individual has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital; and 3.3.2 Either:
        - 3.3.2.1 The individual has experienced intolerable side effects with rituximab; or
        - 3.3.2.2 At four months following the initial course of rituximab the individual has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Renewal — (Rheumatoid Arthritis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Following 6 months' initial treatment, the individual has experienced at least a 50% decrease in active joint count from baseline; or
- 2 On subsequent reapplications, the individual has experienced at least a continuing 30% improvement in active joint count

Subsidy		Fully	Brand or	
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from baseline.

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

Either:

- 1 Individual is currently on treatment with upadacitinib for atopic dermatitis and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Individual has moderate to severe atopic dermatitis, severity as defined by an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 or a Dermatology Life Quality Index (DLQI) score of greater than or equal to 10; and
  - 2.2 Individual has received insufficient benefit from topical therapy (including topical corticosteroids or topical calcineurin inhibitors) for a 28-day trial within the last 6 months, unless contraindicated to all; and
  - 2.3 Individual has trialled and received insufficient benefit from at least one systemic therapy for a minimum of three months (eg ciclosporin, azathioprine, methotrexate or mycophenolate mofetil), unless contraindicated to all; and
  - 2.4 An EASI assessment or 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
  - 2.5 The most recent EASI or DQLI assessment is no more than 1 month old at the time of application.

**Renewal** — (atopic dermatitis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 Individual has received a 75% or greater reduction in EASI score (EASI 75) as compared to baseline EASI prior to commencing upadacitinib; or
- 2 Individual has received a DLQI improvement of 4 or more as compared to baseline DLQI prior to commencing upadacitinib.

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

Either:

- 1 Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment; or
- 2 Both:
  - 2.1 Individual has active Crohn's disease; and
  - 2.2 Either:
    - 2.2.1 Individual has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Individual meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      - 2.2.2.2 Other biologic therapies for Crohn's disease are contraindicated.

Renewal — (Crohn's disease - adult) 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 when the individual was initiated on biologic therapy; or
- 2 HBI score has reduced by 3 points from when individual was initiated on biologic therapy; or
- 3 CDAI score is 150 or less; or
- 4 HBI score is 4 or less; or
- 5 The individual has experienced an adequate response to treatment, but CDAI score cannot be assessed.

Initial application - (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 6 months for applications

	Subsidy	F	ully	Brand or
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meeting the following criteria:

Either:

- 1 Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment; or
- 2 Both:
  - 2.1 Child has active Crohn's disease; and
  - 2.2 Either:
    - 2.2.1 Child has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Child meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      - 2.2.2.2 Other biologic therapies for Crohn's disease are contraindicated.

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 child was initiated on treatment; or
- 2 PCDAI score is 15 or less; or
- 3 The child has experienced an adequate response to treatment, but PCDAI score cannot be assessed.
- Note: Indications marked with \* are unapproved indications.

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

Either:

1 Individual is currently on treatment with upadacitinib for ulcerative colitis and met all remaining criteria prior to commencing treatment; or

- 2 Both:
  - 2.1 Individual has active ulcerative colitis; and
  - 2.2 Either:
    - 2.2.1 Individual has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Individual meets the initiation criteria for prior biologic therapies for ulcerative colitis; and
      - 2.2.2.2 Other biologic therapies for ulcerative colitis are contraindicated.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 The SCCAI score has reduced by 2 points or more from the SCCAI score when the individual was initiated on treatment; or
- 2 PUCAI score has reduced by 10 points or more from the PUCAI score when the individual was initiated on treatment.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Antiallergy Preparations				
Allergic Emergencies				
<ul> <li>ADRENALINE – Special Authority see SA2185 below – Retail p</li> <li>a) Maximum of 2 inj per prescription</li> <li>b) Additional prescriptions limited to replacement of up to the treatment of anaphylaxis.</li> </ul>		piry, c	or replaceme	nt of used device for
Inj 0.15 mg per 0.3 ml auto-injector Inj 0.3 mg per 0.3 ml auto-injector		1 OF 1 OF		pipen Jr pipen
SA2185 Special Authority for Subsidy Initial application — (anaphylaxis) from any relevant practitio applications meeting the following criteria: Both:	ner. Approvals valid	withou	ut further ren	ewal unless notified for
<ol> <li>Either:         <ol> <li>Patient has experienced an anaphylactic reaction department; or</li> <li>Patient has been assessed to be at significant risi</li> </ol> </li> <li>Patient is not to be prescribed more than two devices in it</li> </ol>	k of anaphylaxis by a			
ICATIBANT – Special Authority see SA1558 below – Retail pha Inj 10 mg per ml, 3 ml prefilled syringe	ırmacy 2,668.00	1		irazyr
Initial application only from a clinical immunologist or relevant : the following criteria: Both:	specialist. Approvals	valid	ior 12 month	s for applications meeting
<ol> <li>Supply for anticipated emergency treatment of laryngeal/ angioedema (HAE) for patients with confirmed diagnosis</li> <li>The patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training and has agreed to the patient has undergone product training agreed to the patient has undergone patien</li></ol>	of C1-esterase inhibited upon an action pla	tor de an for	ficiency; and self-adminis	tration.
<b>Renewal</b> from any relevant practitioner. Approvals valid for 12 is benefiting from treatment.	months where the trea	atmen	t remains ap	propriate and the patient

### Allergy Desensitisation

#### ► SA1367 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria: Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

Renewal only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

BEE VENOM ALLERGY TREATMENT - Special Authority see SA1367 above - Retail pharmacy

Initiation kit - 1 vial 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 \$29
Maintenance kit - 6 vials 120 mcg freeze dried venom, with			
diluent	285.00	1 OP	<ul> <li>Venomil S29</li> </ul>
Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent			
9 ml, 3 diluent 1.8 ml	334.39	1 OP	<ul> <li>Albey</li> </ul>
Treatment kit - 1 vial 550 mcg freeze dried venom, with diluent	305.00	1 OP	<ul> <li>Hymenoptera S29</li> </ul>

266

	Subsidy		Fully Brand or
	(Manufacturer's Pr	ice) Subsi	
	(Manalactoror 511	Per	Manufacturer
	Ŷ		
WASP VENOM ALLERGY TREATMENT – Special Authority see	e SA1367 on the p	previous page -	<ul> <li>Retail pharmacy</li> </ul>
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze			
dried polistes venom, 1 diluent 9 ml, 3 diluent 1.8 ml	383.33	1 OP	<ul> <li>Albey</li> </ul>
		101	• Albey
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze			
dried venom, with diluent		1 OP	<ul> <li>Hymenoptera S29</li> </ul>
Treatment kit (Paper wasp venom) - 6 vials 120 mcg freeze			
dried venom, with diluent		1 OP	Venomil S29
Treatment kit (Yellow Jacket venom) - 1 vial 550 mcg freeze			
dried venom, with diluent		1 OP	<ul> <li>Hymenoptera S29</li> </ul>
		TOP	<ul> <li>Hymenoptera 325</li> </ul>
Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze			_
dried vespula venom, 1 diluent 9 ml, 3 diluent 1.8 ml		1 OP	<ul> <li>Albey</li> </ul>
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze	9		
dried venom, with diluent		1 OP	<ul> <li>Venomil S29</li> </ul>
Antihistamines			
CETIRIZINE HYDROCHLORIDE			
★ Tab 10 mg	1 71	100	✓ Zista
Oral liq 1 mg per ml		200 ml	<ul> <li>Histaclear</li> </ul>
DEXTROCHLORPHENIRAMINE MALEATE			
🖌 Tab 2 mg	2.02	40	
C C	(8.40)		Polaramine
	1.01	20	
	(5.99)	20	Polaramine
✤ Oral lig 2 mg per 5 ml		100 ml	Tolaramine
K Oral liq 2 mg per 5 ml		100 111	Dalamania
	(10.29)		Polaramine
EXOFENADINE HYDROCHLORIDE			
* Tab 60 mg	4.34	20	
· ····································	(8.23)		Telfast
₭ Tab 120 mg	( )	30	✓ Fexaclear
k Tab 180 mg		30	✓ Fexaclear
5	4.10	30	• <u>rexaclear</u>
ORATADINE			
🖌 Tab 10 mg	1.78	100	<ul> <li>Lorafix</li> </ul>
🖌 Oral liq 1 mg per ml		100 ml	<ul> <li>Haylor syrup</li> </ul>
			.,,.
	0.40	100	
₭ Tab 10 mg		100	<ul> <li>Allersoothe</li> </ul>
₭ Tab 25 mg		100	<ul> <li>Allersoothe</li> </ul>
K Oral liq 1 mg per 1 ml		100 ml	<ul> <li>Allersoothe</li> </ul>
Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a F	PSO21.09	5	<ul> <li>Hospira</li> </ul>
			-
Inhaled Corticosteroids			
BECLOMETHASONE DIPROPIONATE			
Aerosol inhaler, 50 mcg per dose	14.01	200 dose OP	✓ Qvar
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose OP	✓ Beclazone 50
			✓ Qvar
Aerosol inhaler, 100 mcg per dose		200 dose OP	
Aerosol inhaler, 100 mcg per dose CFC-free		200 dose OP	<ul> <li>Beclazone 100</li> </ul>
Aerosol inhaler, 250 mcg per dose CFC-free	22.67	200 dose OP	<ul> <li>Beclazone 250</li> </ul>

Subsidy		Fully	
(Manufacturer's		ubsidised	I Generic Manufacturer
ې م	Fei	•	Manulacturer
17.00			
17.00	200 dose (	OP ▼	Pulmicort
10.00	000 daaa (		Turbuhaler
	200 dose (	)P 🔮	Pulmicort Turbuhaler
22.00	200 doco (		Pulmicort
	200 0036 0	•	Turbuhaler
			Turbundion
7 19	120 dose (	)P 🗸	Flixotide
			Flixotide Accuhaler
			Flixotide Accuhaler
	120 dose (	DP 🗸	Flixotide
24.62	120 dose (	DP 🗸	Flixotide
11.93	60 dose C	P 🗸	Flixotide Accuhaler
nists			
069) 10.32	60 doso ()	D	
,	00 0056 0	Г	Oxis Turbuhaler
(10.00)			
61.00	20 doco O	D 🖌	Onbrez Breezhaler
			Onbrez Breezhaler
	00 0030 0		Onbiez Diceznaici
26.25	120 doco (		Serevent
			Serevent Accuhaler
a-Adrenocept	tor Agonis	sts	
e with		_	
41.50	120 dose (	DP 🗸	DuoResp Spiromax
41.50 marate	120 dose (	)P 🗸	DuoResp Spiromax
41.50 narate mcg	120 dose (	)P 🗸	DuoResp Spiromax
41.50 narate mcg 2			
41.50 narate mcg 2 	120 dose (	)P 🗸	DuoResp Spiromax
41.50 marate mcg 	120 dose ( 120 dose (	)P 🗸	DuoResp Spiromax Vannair
41.50 narate mcg 2 	120 dose (	)P 🗸	DuoResp Spiromax Vannair Symbicort
	120 dose ( 120 dose ( 120 dose (	)P ✓ )P ✓ )P ✓	DuoResp Spiromax Vannair Symbicort Turbuhaler 100/6
	120 dose ( 120 dose (	)P ✓ )P ✓ )P ✓	DuoResp Spiromax Vannair Symbicort Turbuhaler 100/6 Vannair
	120 dose ( 120 dose ( 120 dose ( 120 dose (	)P ✓ )P ✓ )P ✓	DuoResp Spiromax Vannair Symbicort Turbuhaler 100/6
	120 dose ( 120 dose ( 120 dose ( 120 dose (	)P ✓ )P ✓ )P ✓	DuoResp Spiromax Vannair Symbicort Turbuhaler 100/6 Vannair Symbicort
	120 dose ( 120 dose ( 120 dose ( 120 dose (	)P ✓ )P ✓ )P ✓	DuoResp Spiromax Vannair Symbicort Turbuhaler 100/6 Vannair Symbicort Turbuhaler 200/6 Symbicort
	120 dose ( 120 dose ( 120 dose ( 120 dose ( 120 dose (	)P ✓ )P ✓ )P ✓	DuoResp Spiromax Vannair Symbicort Turbuhaler 100/6 Vannair Symbicort Turbuhaler 200/6
	120 dose ( 120 dose ( 120 dose ( 120 dose ( 120 dose (	)P ✓ )P ✓ )P ✓	DuoResp Spiromax Vannair Symbicort Turbuhaler 100/6 Vannair Symbicort Turbuhaler 200/6 Symbicort
	\$	\$         Per	\$         Per

	Subsidy		Full	y Brand or
	(Manufacturer's	Price)	Subsidise	d Generic
	\$	Pe	er 🗸	Manufacturer
FLUTICASONE WITH SALMETEROL				
	05 70	100 -		Seretide
Aerosol inhaler 50 mcg with salmeterol 25 mcg		120 dos		
Aerosol inhaler 125 mcg with salmeterol 25 mcg		120 dos	se OP 🗸	Seretide
Powder for inhalation 100 mcg with salmeterol 50 mcg - No				
more than 2 dose per day	33.74	60 dos	e OP 🖌	Seretide Accuhaler
Powder for inhalation 250 mcg with salmeterol 50 mcg – No		00 000		
<b>o o</b>	44.00	00 .1		
more than 2 dose per day		60 dos	e OP 🗸	Seretide Accuhaler
Data Advancember Anoniata				
Beta-Adrenoceptor Agonists				
SALBUTAMOL				
Oral liq 400 mcg per ml	50.00	150		Ventelin
				Ventolin
Infusion 1 mg per ml, 5 ml		10		Ventolin
Inj 500 mcg per ml, 1 ml – Up to 5 inj available on a PSO	130.00	5	✓	Ventolin
Inhaled Beta-Adrenoceptor Agonists				
SALBUTAMOL				
Aerosol inhaler, 100 mcg per dose CFC free – Up to 1000				
dose available on a PSO		200 dos	se OP 🗸	' SalAir
	(6.80)			Ventolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule - Up to 30 neb				
available on a PSO	8 96	20		' Asthalin
	0.00	20	•	Asthann
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb				
available on a PSO	9.43	20	<b>v</b>	' Asthalin
TERBUTALINE SULPHATE				
Powder for inhalation, 200 mcg per dose (equivalent to	00.00	400 .1.		
250 mcg metered dose), breath activated		120 dos	se OP 🗸	Bricanyl Turbuhaler
Antich elizovaie Avente				
Anticholinergic Agents				
IPRATROPIUM BROMIDE				
Aerosol inhaler, 20 mcg per dose CFC-free	16.20	200 dos		Atrovent
	10.20	200 008		Allovent
<ul> <li>a) Up to 400 dose available on a PSO</li> </ul>				
<ul> <li>b) No patient co-payment payable</li> </ul>				
Nebuliser soln, 250 mcg per ml, 2 ml ampoule - Up to 40 ne	b			
available on a PSO		20		Accord S29
		20		' Univent
			•	Univent
Inhaled Beta-Adrenoceptor Agonists with Anticl	holinergic /	Agents		
SALBUTAMOL WITH IPRATROPIUM BROMIDE				
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg p			~ ~	
dose CFC-free	12.19	200 dos	se 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		20	<b>•</b>	' Duolin
,				

	Subsidy (Manufacturer's Price) \$		Fully dised	Brand or Generic Manufacturer
Long-Acting Muscarinic Antagonists				
<ul> <li>GLYCOPYRRONIUM – Subsidy by endorsement <ul> <li>a) Inhaled glycopyrronium treatment will not be subsidised i umeclidinium.</li> <li>b) Glycopyrronium powder for inhalation 50 mcg per dose is having COPD using spirometry if spirometry is possible, a Powder for inhalation 50 mcg per dose</li></ul></li></ul>	subsidised only for p and the prescription is 	batients who s endorsed dose OP at with subsi	o have accord ✓ S idised i OPD u tropiur	been diagnosed as lingly. <b>eebri Breezhaler</b> inhaled glycopyrronium or using spirometry if
<ul> <li>a) Umeclidinium will not be subsidised if patient is also rece tiotropium bromide.</li> <li>b) Umeclidinium powder for inhalation 62.5 mcg per dose is COPD using spirometry if spirometry is possible, and the Powder for inhalation 62.5 mcg per dose</li> </ul>	subsidised only for p prescription is endor	atients who	have ngly.	
Long-Acting Muscarinic Antagonists with Long	-Acting Beta-Ac	Irenocep	tor A	gonists

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).

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

# Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist

BUDESONIDE WITH GLYCOPYRRONIUM AND EFORMOTEROL – Special Authority see SA2421 on the next page – Retail pharmacy

Aerosol inhaler budesonide 160 mcg with glycopyrronium

Subsidy	Fu	lly	Brand or
(Manufacturer's Price)	Subsidis	ed	Generic
\$	Per	1	Manufacturer

### ⇒SA2421 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 a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA); and
    - 2.1.2 Any of the following:

Clinical criteria:

- 2.1.2.1 Patient has a COPD Assessment Test (CAT) score greater than 10; or
- 2.1.2.2 Patient has had 2 or more exacerbations in the previous 12 months; or
- 2.1.2.3 Patient has had one exacerbation requiring hospitalisation in the previous 12 months; or
- 2.1.2.4 Patient has had an eosinophil count greater than or equal to 0.3 × 10<sup>9</sup> cells/L in the previous 12 months; or
- 2.2 Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long-acting muscarinic antagonist and long-acting beta-2 agonist ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler therapy.

FLUTICASONE FUROATE WITH UMECLIDINIUM AND VILANTEROL – Special Authority see SA2326 below – Retail pharmacy Powder for inhalation fluticasone furoate 100 mcg with

umeclidinium 62.5 mcg and vilanterol 25 mcg...... 104.24 30 dose OP 🗸 Trelegy Ellipta

### ⇒SA2326 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 a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA); and
    - 2.1.2 Any of the following:
      - Clinical criteria:
      - 2.1.2.1 Patient has a COPD Assessment Test (CAT) score greater than 10; or
      - 2.1.2.2 Patient has had 2 or more exacerbations in the previous 12 months; or
      - 2.1.2.3 Patient has had one exacerbation requiring hospitalisation in the previous 12 months; or
      - 2.1.2.4 Patient has had an eosinophil count greater than or equal to 0.3 × 10°9 cells/L in the previous 12 months; or
  - 2.2 Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long acting muscarinic antagonist and long acting beta-2 agonist ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler triple therapy.

### Antifibrotics

NINTEDANIB - Special Authority see SA2012 on the next page -	Retail pharmacy		
Note: Nintedanib not subsidised in combination with subsidise	d pirfenidone.		
Cap 100 mg	2,554.00	60 OP	<ul> <li>Ofev</li> </ul>
Cap 150 mg	3,870.00	60 OP	<ul> <li>Ofev</li> </ul>

Subsidy	Full	/ Brand or
(Manufacturer's Price)	Subsidise	I 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 su	ubsidised nintedanib		
Tab 801 mg		90 OP	<ul> <li>Esbriet</li> </ul>
Tab 267 mg	1,215.00	90	<ul> <li>Esbriet</li> </ul>

#### 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		Fully Brand or
	(Manufacturer's Pric	ce) Sub Per	sidised Generic Manufacturer
Leukotriene Receptor Antagonists			
ONTELUKAST			
Tab 4 mg		28	<ul> <li>Montelukast Viatris</li> </ul>
Tab 5 mg		28	<ul> <li>Montelukast Viatris</li> </ul>
Tab 10 mg	2.45	28	<ul> <li>Montelukast Viatris</li> </ul>
<b>Nethylxanthines</b>			
/INOPHYLLINE			
Inj 25 mg per ml, 10 ml ampoule – Up to 5 inj available on a			
PSO	180.00	5	<ul> <li>DBL Aminophylline</li> </ul>
IEOPHYLLINE		Ū	
Tab long-acting 250 mg		100	✓ Nuelin-SR
Oral liq 80 mg per 15 ml		500 ml	✓ Nuelin
lucolytics			
RNASE ALFA – Special Authority see SA1978 below – Retail	pharmacy		
Nebuliser soln, 2.5 mg per 2.5 ml ampoule		6	<ul> <li>Pulmozyme</li> </ul>
of the following: 1 Patient has a confirmed diagnosis of cystic fibrosis; and 2 Patient has previously undergone a trial with, or is current	v being treated wi	th. hypertoni	c saline: and
3 Any of the following:	, 2011.g 1.001.00	,, portor	
<ul><li>3.1 Patient has required one or more hospital inpatient</li><li>3.2 Patient has had 3 exacerbations due to CF, requiring</li></ul>			
period; or 3.3 Patient has had 1 exacerbation due to CF, requiring Brasfield score of < 22/25; or	g oral or IV antibio	tics in the pr	evious 12 month period and a
3.4 Patient has a diagnosis of allergic bronchopulmona	ary aspergillosis (A	BPA).	
<b>newal</b> — (cystic fibrosis) only from a respiratory physician o iffied where the treatment remains appropriate and the patient			
EXACAFTOR WITH TEZACAFTOR, IVACAFTOR AND IVACA		y – Special /	Authority see SA2456 below
Tab elexacaftor 50 mg with tezacaftor 25 mg, ivacaftor 37.5 m			
(56) and ivacaftor 75 mg (28)		84 OP	<ul> <li>Trikafta</li> </ul>
Tab elexacaftor 100 mg with tezacaftor 50 mg, ivacaftor 75 m			Trillette
(56) and ivacaftor 150 mg (28)	21,041.39	84 OP	<ul> <li>Trikafta</li> </ul>
SA2456 Special Authority for Subsidy tial application from any relevant practitioner. Approvals valic e following criteria: of the following:	d without further re	enewal unles	s notified for applications meet
1 Patient has been diagnosed with cystic fibrosis; and			

- 1 Patient has been diagnosed with cystic fibrosis; and
- 2 Patient is 6 years of age or older; and
- 3 Either:

▲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

	· · · <b>/</b>		Brand or
(Manufactu	Irer's Price) Subsid	ised	Generic
	\$Per	✓	Manufacturer

#### continued...

- 3.1 Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele); or
- 3.2 Patient has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
- 4 Either:
  - 4.1 Patient has a heterozygous or homozygous F508del mutation; or
  - 4.2 Patient has a G551D mutation or other mutation responsive in vitro to elexacaftor/tezacaftor/ivacaftor (see note a); and
- 5 The treatment must be the sole funded CFTR modulator therapy for this condition; and
- 6 Treatment with elexacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition.

#### Notes:

 a) Eligible mutations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information <u>https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/f354423a-85c2-41c3-a9db-0f3aee135d8d/spl-doc</u>

#### IVACAFTOR - PCT only - Specialist - Special Authority see SA2017 below

Tab 150 mg	 56	Kalydeco
Oral granules 50 mg, sachet	 56	Kalydeco
Oral granules 75 mg, sachet	 56	<ul> <li>Kalydeco</li> </ul>

### ⇒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 and S549R) in the CFTR gene on at least 1 allele; and
- 3 Patients must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
- 4 Treatment with ivacaftor must be given concomitantly with standard therapy for this condition; and
- 5 Patient must not have an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing treatment with ivacaftor; and
- 6 The dose of ivacaftor will not exceed one tablet or one sachet twice daily; and
- 7 Applicant has experience and expertise in the management of cystic fibrosis.

#### SODIUM CHLORIDE

Not funded for use as a nasal drop. Soln 7%25.73	90 ml OP	✓ Biomed
Nasal Preparations		
Allergy Prophylactics		
BUDESONIDE		
Metered aqueous nasal spray, 50 mcg per dose	200 dose OP	<ul> <li>SteroClear</li> </ul>
Metered aqueous nasal spray, 100 mcg per dose	200 dose OP	✓ SteroClear
FLUTICASONE PROPIONATE		
Metered aqueous nasal spray, 50 mcg per dose2.57	120 dose OP	<ul> <li>Flixonase Hayfever &amp; Allergy</li> </ul>

	Subsidy (Manufacturer's P \$	rice) Subs Per	Fully Brand or idised Generic ✔ Manufacturer
IPRATROPIUM BROMIDE Aqueous nasal spray, 0.03%	5.23	15 ml OP	✓ Univent
Respiratory Devices			
MASK FOR SPACER DEVICE			
a) Up to 50 dev available on a PSO			
<ul><li>b) Only on a PSO</li><li>c) Only for children aged six years and under</li></ul>			
Small	2.70	1	<ul> <li>e-chamber Mask</li> </ul>
PEAK FLOW METER			
a) Up to 25 dev available on a PSO			
b) Only on a PSO Low range		1	Mini-Wright AFS
			Low Range
Normal range	9.54	1	<ul> <li>Mini-Wright Standard</li> </ul>
SPACER DEVICE			
<ul> <li>a) Up to 50 dev available on a PSO</li> <li>b) Only on a PSO</li> </ul>			
220 ml (single patient)	3.65	1	<ul> <li>e-chamber Turbo</li> </ul>
510 ml (single patient)		1	<ul> <li>e-chamber La</li> </ul>
800 ml	6 50	1	Grande ✓ Volumatic
000 111	0.50	I	
Respiratory Stimulants			
CAFFEINE CITRATE			
Oral liq 20 mg per ml (10 mg base per ml)	16.91	25 ml OP	<ul> <li>Biomed</li> </ul>

(Manufacturer's Price)       Subsidied       Generic         Server       Manufacturer             Ear Arpeparations             FUMETASONE PIVALATE    Ear drops 0.02% with clioquinol 1%		Subsidy		Fully Brand or
s       Per       Manufacturer         Ear Preparations         FLUMETASONE PIVALATE         Ear drops 0.02% with cliquinol 1%			ice) Subs	,
LUMETASONE PIVALATE         Ear drops 0.02% with cliquinol 1%				
Ear drops 0.02% with clioquinol 1%	Ear Preparations			
ED's ✓ Locorten-Vioform         FRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g       5.16       7.5 ml OP       ✓ Kenacomb <b>Ear/Eye Preparations</b> DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml       4.50       8 ml OP (9.27)       Otodex (####################################	FLUMETASONE PIVALATE			
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN         Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate         2.5 mg and gramicidin 250 mcg per g         Ear/Eye Preparations         DeXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN         Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and         gramicidin 50 mcg per ml         (9.27)         Otodex ***         Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml to be delisted 1 November (9.27)         Otodex ***         Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml to be delisted 1 November (9.27)         Sofradex         Otodex ***         Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml to be delisted 1 November (9.27)         Otodex ***         Ear/Eye drops 0.5%         .4.13       8 ml OP         (8.65)       Soframycin         Eye preparations         Eye oring 3%       15.89       4.5 g OP       ✓ ViruPOS         CHLORNPHENICOL         Eye drops 0.5%       1.09       5 g OP       ✓ Devatis         Eye drops 0.5%       1.09       5 g OP       ✓ Diorsig         Funded for use in the ear*. Indications marked with * are unapproved indications.       SPROFLOXACIN <tr< td=""><td>Ear drops 0.02% with clioquinol 1%</td><td>4.46</td><td>7.5 ml OP</td><td></td></tr<>	Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP	
Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g				<ul> <li>Locorten-Vioform</li> </ul>
2.5 mg and gramicidin 250 mcg per g	TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYC	IN AND NYSTATI	Ν	
Ear/Eye Preparations         DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN         Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml				
DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml	2.5 mg and gramicidin 250 mcg per g	5.16	7.5 ml OP	<ul> <li>Kenacomb</li> </ul>
Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml       4.50       8 ml OP         (9.27)       Sofradex         Olodex @@       Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml to be delisted 1 November 2025)         "FRAMYCETIN SULPHATE         Ear/Eye drops 0.5%       4.13       8 ml OP         (8.65)       Soframycin         Eye preparations       4.13       8 ml OP         (8.65)       Soframycin         Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.         Anti-Infective Preparations         CICLOVIR         * Eye oint 3%       15.89       4.5 g OP       ✓ ViruPOS         CHLORAMPHENICOL       10.9       5 g OP       ✓ Devatis         Eye drops 0.5%       1.45       10 ml OP       ✓ Chlorsig         Funded for use in the ear*. Indications marked with * are unapproved indications.       CIProfloxacin Teva         When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]       5.29       5 g OP       ✓ Fucithalmic         Eye drops 1%       5.3	Ear/Eye Preparations			
Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml       4.50       8 ml OP         (9.27)       Sofradex         Olodex @@       Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml to be delisted 1 November 2025)         "FRAMYCETIN SULPHATE         Ear/Eye drops 0.5%       4.13       8 ml OP         (8.65)       Soframycin         Eye preparations       4.13       8 ml OP         (8.65)       Soframycin         Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.         Anti-Infective Preparations         CICLOVIR         * Eye oint 3%       15.89       4.5 g OP       ✓ ViruPOS         CHLORAMPHENICOL       10.9       5 g OP       ✓ Devatis         Eye drops 0.5%       1.45       10 ml OP       ✓ Chlorsig         Funded for use in the ear*. Indications marked with * are unapproved indications.       CIProfloxacin Teva         When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]       5.29       5 g OP       ✓ Fucithalmic         Eye drops 1%       5.3	DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN			
(9.27)       Otodex \$\$\$\$\$ Sofradex         (9.27)       Sofradex         Otodex \$\$\$\$\$ Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml to be delisted 1 November 2025)         FRAMYCETIN SULPHATE         Ear/Eye drops 0.5%				
(9.27) Sofradex Otodex Sear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml to be delisted 1 November 2025) FRAMYCETIN SULPHATE Ear/Eye drops 0.5%	gramicidin 50 mcg per ml	4.50	8 ml OP	
Otodex ****       Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml to be delisted 1 November 2025)         "RAMYCETIN SULPHATE       4.13       8 ml OP         Ear/Eye drops 0.5%       4.13       8 ml OP         (8.65)       Soframycin         Eye preparations         Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.         Anti-Infective Preparations         ACICLOVIR         * Eye oint 3%       15.89       4.5 g OP <u>ViruPOS</u> CHLORAMPHENICOL         Eye drops 0.5%       1.09       5 g OP              Devatis         Eye drops 0.5%       1.01cations marked with * are unapproved indications.              Chlorsig         Funded for use in the ear*. Indications marked with * are unapproved indications.              Cliprofloxacin Teva         When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative oittis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]              5.29       5 g OP              Fucithalmic              Fucithalmic              Fucithalmic S29 ***********************************		( )		
2025)         FRAMYCETIN SULPHATE         Ear/Eye drops 0.5%         Ear/Eye drops 0.5%         (8.65)         Soframycin         Eye Preparations         Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.         Anti-Infective Preparations         ACICLOVIR         * Eye oint 3%         * Eye oint 3%		( )		
Ear/Eye drops 0.5%       4.13       8 ml OP         (8.65)       Soframycin         Eye Preparations       Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.         Anti-Infective Preparations         ACICLOVIR         * Eye oint 3%       15.89         4.5 g OP       ✓ ViruPOS         CHLORAMPHENICOL         Eye drops 0.5%       1.45         Funded for use in the ear*. Indications marked with * are unapproved indications.         CIPROFLOXACIN         Eye drops 0.3%       Sbisidy by endorsement.         Eye drops 0.3%       Sbisidy by endorsement.         UPROFLOXACIN         Eye drops 1.3%       S g OP         Vhen prescribed for the treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly.         Note:       Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]       Eye drops 1%       S g OP       ✓ Fucithalmic         Eye oint 0.3%       S g OP       ✓ Tobre	(Otodex <sup>629</sup> Ear/Eye drops 500 mcg with framycetin sulphate 5 2025)	5 mg and gramicid	lin 50 mcg per	ml to be delisted 1 November
(8.65)       Soframycin         Eye Preparations         Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.         Anti-Infective Preparations         ACICLOVIR         * Eye oint 3%       15.89       4.5 g OP       ViruPOS         CHLORAMPHENICOL       1.09       5 g OP       Devatis         Eye oint 1%       1.45       10 ml OP       Chlorsig         Funded for use in the ear*. Indications marked with * are unapproved indications.       Cliprofloxacin Teva         CIPROFLOXACIN       Eye drops 0.3%       Solid by endorsement.       10.85       5 ml OP       Ciprofloxacin Teva         When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.       SODIUM FUSIDATE [FUSIDIC ACID]       Eye drops 1%       So g OP       Fucithalmic         Eye oint 0.3%       5.29       5 g OP       Fucithalmic       Fucithalmic         COBRAMYCIN       Eye oint 0.3%       10.45       3.5 g OP       Tobrex	FRAMYCETIN SULPHATE			
Eye Preparations         Anti-Infective Preparations         AciCLOVIR         * Eye oint 3%       15.89       4.5 g OP       ViruPOS         CHLORAMPHENICOL         Eye oint 1%       1.09       5 g OP       Devatis         Eye drops 0.5%       1.45       10 ml OP       Chlorsig         Funded for use in the ear*. Indications marked with * are unapproved indications.       CIPROFLOXACIN       Eye drops 0.3%       S ml OP       Ciprofloxacin Teva         When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]         Eye drops 1%       5.29       5 g OP       ✓ Fucithalmic         Eye drops 10.3%	Ear/Eye drops 0.5%		8 ml OP	
Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.  Anti-Infective Preparations  ACICLOVIR  * Eye oint 3%		(8.65)		Soframycin
Anti-Infective Preparations         ActicLOVIR         ★ Eye oint 3%         ★ Eye oint 3%         LORAMPHENICOL         Eye oint 1%         Eye oint 1%         Log of the second line treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]         Eye drops 1%         Eye drops 1%         COBRAMYCIN         Eye oint 0.3%	Eye Preparations			
Anti-Infective Preparations         ActicLOVIR         ★ Eye oint 3%         ★ Eye oint 3%         LORAMPHENICOL         Eye oint 1%         Eye oint 1%         Log of the second line treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]         Eye drops 1%         Eye drops 1%         COBRAMYCIN         Eye oint 0.3%	For any setting one only founded for use in the one operations and			
ACICLOVIR ★ Eye oint 3%		citry stated otherw	lise.	
<ul> <li>* Eye oint 3%</li></ul>	Anti-Infective Preparations			
<ul> <li>* Eye oint 3%</li></ul>	ACICLOVIR			
Eye oint 1%       1.09       5 g OP       ✓ Devatis         Eye drops 0.5%       1.45       10 ml OP       ✓ Chlorsig         Funded for use in the ear*. Indications marked with * are unapproved indications.       ✓ Chlorsig         CIPROFLOXACIN       10.85       5 ml OP       ✓ Ciprofloxacin Teva         When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]       5.29       5 g OP       ✓ Fucithalmic         Eye drops 1%       5.29       5 g OP       ✓ Fucithalmic         COBRAMYCIN       Eye oint 0.3%       10.45       3.5 g OP       ✓ Tobrex			4.5 g OP	✓ ViruPOS
Eye drops 0.5%       1.45       10 ml OP       ✓ Chlorsig         Funded for use in the ear*. Indications marked with * are unapproved indications.       Image: Cliprofloxacin Teva         CIPROFLOXACIN       10.85       5 ml OP       ✓ Ciprofloxacin Teva         When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]       5 g OP       ✓ Fucithalmic         Eye drops 1%       5 g OP       ✓ Fucithalmic S29 \$29         TOBRAMYCIN       Eye oint 0.3%       10.45       3.5 g OP       ✓ Tobrex	CHLORAMPHENICOL		•	
Funded for use in the ear*. Indications marked with * are unapproved indications.         CIPROFLOXACIN         Eye drops 0.3% - Subsidy by endorsement	Eye oint 1%	1.09	5 g OP	✓ Devatis
CIPROFLOXACIN Eye drops 0.3% - Subsidy by endorsement				<ul> <li>Chlorsig</li> </ul>
Eye drops 0.3% - Subsidy by endorsement		e unapproved ind	ications.	
When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.         SODIUM FUSIDATE [FUSIDIC ACID]       5 g OP       ✓ Fucithalmic         Eye drops 1%				
for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication. SODIUM FUSIDATE [FUSIDIC ACID] Eye drops 1%			• ···· • ·	
Note: Indication marked with a * is an unapproved indication. SODIUM FUSIDATE [FUSIDIC ACID] Eye drops 1%	•			
GODIUM FUSIDATE [FUSIDIC ACID]         Eye drops 1%         Fucithalmic         Fucithalmic S29 \$20         FOBRAMYCIN         Eye oint 0.3%			, and the pies	onpaon io endorsed accordingly.
Eye drops 1%       5 g OP       ✓ Fucithalmic         ✓ Fucithalmic S29 \$23         FOBRAMYCIN         Eye oint 0.3%       10.45       3.5 g OP       ✓ Tobrex				
✓ Fucithalmic S29 529 FOBRAMYCIN Eye oint 0.3%		5.29	5 g OP	<ul> <li>Fucithalmic</li> </ul>
Eye oint 0.3% 10.45 3.5 g OP 🖌 Tobrex			0 -	
Eye oint 0.3% 10.45 3.5 g OP 🖌 Tobrex				
	TOBRAMYCIN			•
Eye arops 0.3% 10brex			0	
	Eye drops 0.3%	11.48	5 MI UP	• IODrex

	Subsidy (Manufacturer's Pri \$	ice) Subs Per	Fully Brand or idised Generic ✓ Manufacturer
Corticosteroids and Other Anti-Inflammatory	Preparations		
DEXAMETHASONE			
* Eye oint 0.1%	5.86	3.5 g OP	<ul> <li>Maxidex</li> </ul>
* Eye drops 0.1%	4.50	5 ml OP	<ul> <li>Maxidex</li> </ul>
Ocular implant 700 mcg - Special Authority see SA1680 b	oelow		
<ul> <li>Retail pharmacy</li> </ul>		1	<ul> <li>Ozurdex</li> </ul>
► SA1680 Special Authority for Subsidy			
<ul> <li>Initial application — (Diabetic macular oedema) only from a meeting the following criteria:</li> <li>All of the following: <ol> <li>Patient has diabetic macular oedema with pseudophaki</li> <li>Patient has reduced visual acuity of between 6/9 - 6/48</li> <li>Either: <ol> <li>1 Patient's disease has progressed despite 3 injec</li> <li>2 Patient is unsuitable or contraindicated to treatm</li> </ol> </li> <li>Dexamethasone implants are to be administered not mo maximum of 3 implants per eye per year.</li> </ol></li></ul>	ic lens; and with functional awar stions with bevacizur tent with anti-VEGF	eness of redu nab; or agents; and	ction in vision; and
Renewal — (Diabetic macular oedema) only from an ophtha the following criteria: Both:	Imologist. Approval	s valid for 12	months for applications meeting
1 Patient's vision is stable or has improved (prescriber de	torminod); and		
<ol> <li>Patient's vision is stable of has improved (prescriber de 2 Dexamethasone implants are to be administered not mo maximum of 3 implants per eye per year.</li> </ol>	<i>,</i> ,	once every 4 n	nonths into each eye, and up to
Initial application — (Women of child bearing age with diat valid for 12 months for applications meeting the following criter		ma) only fron	n an ophthalmologist. Approvals

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	3.5 g OP	<ul> <li>Maxitrol</li> </ul>
Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per ml4.50	5 ml OP	<ul> <li>Maxitrol</li> </ul>
DICLOFENAC SODIUM Eye drops 0.1%, single dose	10 dose 30 dose	<ul> <li>✓ <u>Diclofenac Devatis</u></li> <li>✓ Diclofenac Devatis</li> </ul>
FLUOROMETHOLONE * Eye drops 0.1%	5 ml OP	✓ FML ✓ Flucon

AThree 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

SENSORY ORGANS

# SENSORY ORGANS

	Subsidy		Fully	Brand or
	(Manufacturer's P	rice) Sub	sidised	Generic
	\$	Per	~	Manufacturer
EVOCABASTINE				
Eye drops 0.5 mg per ml	8.71	4 ml OP		
, i oi	(10.34)		L	ivostin
LODOXAMIDE				
Eye drops 0.1%	8.71	10 ml OP	✓ L	omide
PREDNISOLONE ACETATE				
Eye drops 1%	6.92	10 ml OP	🗸 P	rednisolone-AFT
	7.00	5 ml OP	🗸 P	Pred Forte
PREDNISOLONE SODIUM PHOSPHATE – Special Authority s	ee SA1715 below	– Retail phar	macy	
Eye drops 0.5%, single dose (preservative free)		20 dose	🖌 N	linims
				Prednisolone
SA1715 Special Authority for Subsidy				
<b>nitial application</b> only from an ophthalmologist or optometrist.	Approvals valid for	or 6 months fo	r applic	ations meeting the

following criteria: Both:

1 Patient has severe inflammation; and

2 Patient has a confirmed allergic reaction to preservative in eye drops.

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

### SODIUM CROMOGLICATE

Eye drops 2%	2.62	10 ml OP	✓ Allerfix
Glaucoma Preparations - Beta Blockers			
BETAXOLOL			
* Eye drops 0.25%	11.80	5 ml OP	<ul> <li>Betoptic S</li> </ul>
* Eye drops 0.5%	7.50	5 ml OP	<ul> <li>Betoptic</li> </ul>
(Betoptic S Eye drops 0.25% to be delisted 1 December 2025)			
(Betoptic Eye drops 0.5% to be delisted 1 December 2025)			

# ★ Eye drops 0.25% 2.42 5 ml OP ✓ Arrow-Timolol ★ Eye drops 0.5% 2.50 5 ml OP ✓ Arrow-Timolol

### **Glaucoma Preparations - Carbonic Anhydrase Inhibitors**

ACETAZOLAMIDE * Tab 250 mg	96	100	✓ Medsurge
5	.03	100	✓ Diamox
Medsurge to be Principal Supply on 1 September 2025 (Diamox Tab 250 mg to be delisted 1 September 2025)			
BRINZOLAMIDE ₩ Eye drops 1%5	.11	5 ml OP	✓ Azopt
DORZOLAMIDE WITH TIMOLOL * Eye drops 2% with timolol 0.5%3	.58	5 ml OP	✓ Dortimopt
Glaucoma Preparations - Prostaglandin Analogues			
BIMATOPROST * Eye drops 0.03%5	.15	3 ml OP	✓ <u>Lumigan</u>

### SENSORY ORGANS

	Subsidy (Manufacturer's F \$	Price) Subs Per	Fully Brand or sidised Generic ✓ Manufacturer
LATANOPROST			
¥ Eye drops 0.005%	2.08	2.5 ml OP	✓ <u>Teva</u>
TRAVOPROST			
* Eye drops 0.004%	6.80	2.5 ml OP	✓ <u>Travatan</u>
Glaucoma Preparations - Other			
BRIMONIDINE TARTRATE			
* Eye drops 0.2%	5.16	5 ml OP	Arrow-Brimonidine
BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE			
* Eye drops 0.2% with timolol maleate 0.5%	7.13	5 ml OP	<ul> <li>Combigan</li> </ul>
LATANOPROST WITH TIMOLOL			-
* Eye drops 0.005% with timolol 0.5%	4.95	2.5 ml OP	Arrow - Lattim
PILOCARPINE HYDROCHLORIDE			
* Eye drops 1%	4.26	15 ml OP	Isopto Carpine
* Eye drops 2%		15 ml OP	Isopto Carpine
* Eye drops 4%		15 ml OP	<ul> <li>Isopto Carpine</li> </ul>
Subsidised for oral use pursuant to the Standard Forme	ulae.		
PILOCARPINE NITRATE			
* Eye drops 2% single dose – Special Authority see SA0895			
below – Retail pharmacy		20 dose	<ul> <li>Minims Pilocarpine</li> </ul>
SA0895 Special Authority for Subsidy			

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

1 Patient has to use an unpreserved solution due to an allergy to the preservative; or

2 Patient wears soft contact lenses.

Note: Minims for a general practice are considered to be "tools of trade" and are not approved as special authority items. **Renewal** from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

### **Mydriatics and Cycloplegics**

ATROPINE SULPHATE * Eye drops 1%	15 ml OP	✓ Atropt
CYCLOPENTOLATE HYDROCHLORIDE * Eye drops 1%25.16	15 ml OP	✓ Cyclogyl
TROPICAMIDE * Eye drops 0.5%	15 ml OP	✓ Mydriacyl
* Eye drops 1%		<ul> <li>Mydriacyl</li> </ul>
Preparations for Tear Deficiency		

For acetylcysteine eye drops refer Standard Formulae, page 283			
HYPROMELLOSE			
* Eye drops 0.5%	19.50	15 ml OP	<ul> <li>Methopt</li> </ul>
HYPROMELLOSE WITH DEXTRAN			
* Eye drops 0.3% with dextran 0.1%	.2.30	15 ml OP	<ul> <li>Poly-Tears</li> </ul>

	Subsidy (Manufacturer's Pric \$	ce) Per	Fully Subsidised	Brand or Generic Manufacturer
Preservative Free Ocular Lubricants				
■ SA2431 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals va the following criteria: Both:	lid without further re	newal u	nless notifie	d for applications meeting
<ol> <li>Confirmed diagnosis by slit lamp or Schirmer test of seven 2 Either:</li> </ol>	ere secretory dry eye	e; and		
<ul><li>2.1 Patient is using eye drops more than four times d</li><li>2.2 Patient has had a confirmed allergic reaction to p</li></ul>				
POLYETHYLENE GLYCOL 400 AND PROPYLENE GLYCOL Eye drops 0.4% and propylene glycol 0.3%, 0.8 ml SODIUM HYALURONATE [HYALURONIC ACID] – Special Au Eye drops 1 mg per ml Hylo-Fresh has a 6 month expiry after opening. The P month is not relevant and therefore only the prescribed	thority see SA2431 13.58 harmacy Procedures	30 above – 10 ml C s Manua	✓ S Retail pharr P ✓ <u>H</u> I restriction	<b>ystane Unit Dose</b> nacy I <b>ylo-Fresh</b> allowing one bottle per
Other Eye Preparations				
NAPHAZOLINE HYDROCHLORIDE * Eye drops 0.1% OLOPATADINE	5.65	15 ml C	)P 🗸 <u>A</u>	Ibalon
Eye drops 0.1% PARAFFIN LIQUID WITH WOOL FAT	2.17	5 ml O	P 🗸 0	Nopatadine Teva
* Eye oint 3% with wool fat 3%	3.63	3.5 g C	)P 🖌 P	oly-Visc
Eye oint 138 mcg per g	3.80	5 g Ol	⊳ <b>√</b> ۷	itA-POS

VARIOUS

	Quitaidu		Fully Decades
	Subsidy (Manufacturer's Prid	ce) Subs	Fully Brand or idised Generic
	\$	Per	<ul> <li>Manufacturer</li> </ul>
Various			
HARMACY SERVICES			
Brand switch fee	4.50	1 fee	<ul> <li>BSF lpca- Hydroxychloroquine</li> </ul>
			<ul> <li>✓ BSF Modafinil Max Health</li> <li>✓ BSF Pazopanib Teva</li> </ul>
<ul> <li>a) May only be claimed once per patient.</li> <li>b) The Pharmacode for BSF lpca-Hydroxychloroquine</li> <li>c) The Pharmacode for BSF Modafinil Max Health is 2</li> <li>d) The Pharmacode for BSF Pazopanib Teva is 27046</li> <li>Immunisation administration fee - flu</li> <li>Immunisation administration fee - other</li> </ul>	2704684 - see also p 692 - see also page 0.00	bage 148	<ul> <li>✓ Immunisation - Flu</li> <li>✓ Immunisation Other</li> </ul>
Immunisation co-administration fee - flu and shingles	0.00	1 fee	<ul> <li>Immunisation Flu and Shingles</li> </ul>
BSF lpca-Hydroxychloroquine Brand switch fee to be delisted BSF Modafinil Max Health Brand switch fee to be delisted 1 Se BSF Pazopanib Teva Brand switch fee to be delisted 1 August	eptember 2025)		
Agents Used in the Treatment of Poisonings			
Antidotes			
CETYLCYSTEINE Inj 200 mg per ml, 10 ml ampoule	42.99 52.88	10	✓ <u>DBL Acetylcysteine</u> ✓ Martindale Pharma
Inj 200 mg per ml, 10 ml vial		10	<ul> <li>Martinuale i nama</li> <li>Hikma</li> <li>Acetylcysteine \$29</li> </ul>
Martindale Pharma Inj 200 mg per ml, 10 ml ampoule to be de	listed 1 November 2	025)	
ALOXONE HYDROCHLORIDE a) Up to 10 inj available on a PSO			
<ul> <li>b) Only on a PSO</li> <li>€ Inj 400 mcg per ml, 1 ml ampoule</li> </ul>	13.29	5	✓ <u>DBL Naloxone</u> <u>Hydrochloride</u>
Removal and Elimination			
HARCOAL			
<ul> <li>Oral liq 50 g per 250 ml</li> <li>a) Up to 250 ml available on a PSO</li> <li>b) Only on a PSO</li> </ul>	43.50	250 ml OP	✓ Carbosorb-X
EFERASIROX – Special Authority see SA1492 on the next p Wastage claimable	· ·	асу	
Tab. 405 was diagonality	276.00	28	<ul> <li>Exjade</li> </ul>
Tab 125 mg dispersible			•
Tab 125 mg dispersible Tab 250 mg dispersible Tab 500 mg dispersible	552.00	28 28	✓ Exjade ✓ Exjade

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

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

### ⇒SA1492 Special Authority for Subsidy

**Initial application** only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: All of the following:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; and
- 2 Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day; and
- 3 Any of the following:
  - 3.1 Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2\*; or
  - 3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or
  - 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	<ul> <li>Ferriprox</li> </ul>
Oral liq 100	mg per 1 m	ıl		266.59	250 ml OP	<ul> <li>Ferriprox</li> </ul>

#### ⇒SA1480 Special Authority for Subsidy

**Initial application** only from a haematologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; or

2 The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia.

### DESFERRIOXAMINE MESILATE

* Inj 500 mg vial	151.31	10	<ul> <li>Deferoxamine Pfizer S29 S29</li> </ul>
	332.88		✓ DBL Desferrioxamine Mesylate for Inj BP
(Deferoxamine Pfizer S29 S29 Inj 500 mg vial to be delisted	d 1 October 2025)		
	50.01	0	
* Inj 200 mg per ml, 5 ml		6	
	(156.71)		Calcium Disodium Versenate

# **Standard Formulae**

ACETYLCYSTEINE EYE DROPS Acetylcysteine inj 200 mg per ml, 10 ml	qs	PHENOBARBITONE SODIUM PAEDIATRIC ORAL mg per ml)	LIQUID (10
Suitable eye drop base	qs	Phenobarbitone Sodium	400 mg
CODEINE LINCTUS (3 mg per 5 ml) Codeine phosphate	60 mg	Glycerol BP Water	4 ml to 40 ml
Glycerol	40 ml	PILOCARPINE ORAL LIQUID	
Preservative	qs	Pilocarpine 4% eye drops	qs
Water	to 100 ml	Preservative	qs
CODEINE LINCTUS (15 mg per 5 ml)		Water (Preservative should be used if quantity supplied is	to 500 ml
Codeine phosphate Glycerol	300 mg 40 ml	than 5 days.)	
Preservative	qs	SALIVA SUBSTITUTE FORMULA	
Water	to 100 ml	Methylcellulose Preservative	5 g qs
FOLINIC MOUTHWASH		Water	to 500 ml
Calcium folinate 15 mg tab	1 tab	(Preservative should be used if quantity supplied is	for more
Preservative	qs	than 5 days. Maximum 500 ml per prescription.)	
Water (Preservative should be used if quantity supplied is	to 500 ml	SODIUM CHLORIDE ORAL LIQUID	
than 5 days. Maximum 500 ml per prescription.)		Sodium chloride inj 23.4%, 20 ml Water	qs qs
METHYL HYDROXYBENZOATE 10% SOLUTION		(Only funded if prescribed for treatment of hyponatr	
Methyl hydroxybenzoate	10 g		,
Propylene glycol	to 100 ml	VANCOMYCIN ORAL SOLUTION (25 mg per ml) Vancomycin 500 mg injection	5 vials
(Use 1 ml of the 10% solution per 100 ml of oral liqu	ud mixture)	Glycerin with sucrose suspension	37.5 ml
OMEPRAZOLE SUSPENSION		Water	to 100 ml
Omeprazole capsules or powder	qs	(Only funded if prescribed for treatment of Clostridiu	um difficile
Sodium bicarbonate powder BP	8.4 g	following metronidazole failure)	
Water	to 100 ml		
PHENOBARBITONE ORAL LIQUID Phenobarbitone Sodium	1		
Glycerol BP	1 g 70 ml		
Water	to 100 ml		

# EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy		Fully	Brand or
	(Manufacturer's Pr		sidised	Generic
	\$	Per		Manufacturer
Extemporaneously Compounded Preparations	and Galenica	ls		
COLLODION FLEXIBLE Note: This product is no longer being manufactured by the determined.				
Collodion flexible		100 ml	✓ PS	SM
COMPOUND HYDROXYBENZOATE – Only in combination Only in extemporaneously compounded oral mixtures. Soln		100 ml	🗸 Mi	dwest
GLYCERIN WITH SODIUM SACCHARIN – Only in combination Suspension		473 ml	🗸 ()ı	a-Sweet SF
GLYCERIN WITH SUCROSE – Only in combination Suspension		473 ml	🗸 0ı	ra-Sweet
GLYCEROL * Liquid – Only in combination Only in extemporaneously compounded oral liquid prep		500 ml	🗸 he	althE Glycerol BP
METHYL HYDROXYBENZOATE Powder		25 g	🖌 Mi	dwest
METHYLCELLULOSE	00.05	100 -	<i></i>	dWest
Powder Suspension – Only in combination		100 g 473 ml		awest a-Plus
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCH Suspension	HARIN – Only in c	ombination 473 ml	✓ Oi	a-Blend SF
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE – Or Suspension		473 ml	🗸 Oi	a-Blend
PHENOBARBITONE SODIUM Powder – Only in combination Only in children up to 12 years		10 g	🗸 Mi	dWest
PROPYLENE GLYCOL				
Only in extemporaneously compounded methyl hydroxyben Liq		n. 500 ml	🖌 Mi	dwest
SODIUM BICARBONATE Powder BP – Only in combination		500 g	🗸 Mi	dwest
Only in extemporaneously compounded omeprazole an	id lansoprazole su	spension.		
SYRUP (PHARMACEUTICAL GRADE) – Only in combination Only in extemporaneously compounded oral liquid preparati	ions			
Liq		500 ml	🗸 Mi	dwest
WATER Tap – Only in combination	0.00	1 ml	🗸 Ta	p water

### SECTION D: SPECIAL FOODS

Fully

Subsidy (Manufacturer's Price)

\$

Subsidised Per ✓ 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:

. Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE SUPPLEMENT – Special Authority see SA1930 above – Hospital pharmacy [HP3]

Powder6.72	400 g OP	<ul> <li>Polycal</li> </ul>
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### **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:

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

CARBOHYDRATE AND FAT S	SUPPLEMENT – Special Author	ity see SA1376 on	the previous pag	je -	Hospital pharmacy [HP3]
Powder (neutral)			400 g OP	1	Duocal Super
			-		Soluble Powder

### Fat

#### ⇒SA2204 Special Authority for Subsidy

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 an inborn error 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

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

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 — (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 SA2204 on the	he previous page – Hos	spital pharmacy	[HP3]
Emulsion (neutral)		200 ml OP	<ul> <li>Calogen</li> </ul>
	38.44	500 ml OP	<ul> <li>Calogen</li> </ul>
Emulsion (strawberry)	15.38		<ul> <li>Calogen</li> </ul>
Oil		500 ml OP	<ul> <li>MCT oil (Nutricia)</li> </ul>
MCT Emulsion, 250 ml		4 OP	<ul> <li>Liquigen</li> </ul>

### 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 - Specia	al Authority see SA1524 above – Hospital ph	armacy [HP3]	
Powder		227 g OP	<ul> <li>Resource</li> </ul>
			Beneprotein
	13.82	225 g OP	<ul> <li>Protifar</li> </ul>

Subsidy	Fu	lly	Brand or
(Manufacturer's Price)	Subsidise	ed	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	see SA1095 above – H	lospital phar	macy [HP3]
Liquid, 500 ml bottle	4.65	1 OP	<ul> <li>Glucerna Select</li> </ul>
DIABETIC ORAL FEED 1KCAL/ML – Special Authority see	SA1095 above – Hospi	tal pharmac	y [HP3]
Liquid (strawberry), 200 ml bottle	2.25	1 OP	✓ Diasip
Liquid (vanilla), 200 ml bottle		1 OP	<ul> <li>Nutren Diabetes</li> </ul>
	2.25		🗸 Diasip

### **Fat Modified Products**

#### ⇒SA2205 Special Authority for Subsidy

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 an inborn error of metabolism. Initial application — (Indications other than errors of inborn metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Either:

- 1 Patient has a chyle leak; or
- 2 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	e SA2205 above – Hospital pha	armacy [HP3]	
Powder			0 400 g OP	🗸 Monogen

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

# 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 - Spec	cial Authority see SA1099 above - H	Hospital pharmacy	/ [HP3]
Powder		400 g OP	<ul> <li>Kindergen</li> </ul>

# **Paediatric Products**

#### ⇒SA1379 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child is aged one to ten years; and
- 2 Any of the following:
  - 2.1 the child is being fed via a tube or a tube is to be inserted for the purposes of feeding; or
  - 2.2 any condition causing malabsorption; or
  - 2.3 faltering growth in an infant/child; or
  - 2.4 increased nutritional requirements; or
  - 2.5 the child is being transitioned from TPN or tube feeding to oral feeding.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for

continued...

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
continued			
applications meeting the following criteria:			
Both:			
<ol> <li>The treatment remains appropriate and the patient is bene 2 General Practitioners must include the name of the dietitia practitioner and date contacted.</li> </ol>			egistered general
PAEDIATRIC ENTERAL FEED 1.5KCAL/ML – Special Authority Liquid, 500 ml bottle			Hospital pharmacy [HP3] Nutrini Energy RTH
PAEDIATRIC ENTERAL FEED 1KCAL/ML - Special Authority s	ee SA1379 on the pro	evious page – Ho	ospital pharmacy [HP3]
Liquid, 500 ml bottle			Pediasure RTH
	4.69	✓ 1	Nutrini RTH
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Specific and State	ecial Authority see SA	A1379 on the pre	vious page – Hospital
pharmacy [HP3]	7 1 4	1 OP 🗸 I	Nutrini Energy Multi
Liquid, 500 ml bottle			Nutrini Energy Multi Fibre
PAEDIATRIC ORAL FEED 1.5KCAL/ML - Special Authority see	SA1379 on the previ	ious page – Hosr	pital pharmacy [HP3]
Liquid (strawberry), 200 ml bottle			Fortini
Liquid (vanilla), 200 ml bottle	1.90	1 OP 🖌 🖌	Fortini
Liquid (vanilla), 500 ml bottle	8.67	1 OP 🖌 I	Pediasure Plus
PAEDIATRIC ORAL FEED 1KCAL/ML - Special Authority see S	A1379 on the previou	us page – Hospit	al pharmacy [HP3]
Liquid (chocolate), 200 ml bottle		1 OP 🖌 I	Pediasure
Liquid (strawberry), 200 ml bottle	1.33	1 OP 🖌 🖌	Pediasure
Liquid (vanilla), 200 ml bottle			Pediasure
Liquid (vanilla), 250 ml can	1.66	1 OP 🖌 I	Pediasure
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML - Special	Authority see SA137	9 on the previou	<mark>s page –</mark> Hospital
pharmacy [HP3]			
Liquid (chocolate), 200 ml bottle			Fortini Multi Fibre
Liquid (strawberry), 200 ml bottle			Fortini Multi Fibre
Liquid (unflavoured), 200 ml bottle			Fortini Multi Fibre
Liquid (vanilla), 200 ml bottle			Fortini Multi Fibre
PEPTIDE-BASED ORAL FEED - Special Authority see SA1379			
Powder		00 g OP 🖌 I	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 ORAL FEED 1.8 KCAL/ML - Special Authority see S	A1101 above – Hosp	oital pharmac	y [HP3]
Liquid, 220 ml bottle	3.31	1 OP	Nepro HP
			(strawberry)
			<ul> <li>Nepro HP (vanilla)</li> </ul>

	Subsidy (Manufacturer's Price) \$	Sub Per	Fully osidised	Brand or Generic Manufacturer
RENAL ORAL FEED 2 KCAL/ML – Special Authority see SA110 Liquid, 200 ml bottle Liquid (apricot) 125 ml		<mark>ge –</mark> Hos 4 OP 4 OP	🧹 N	macy [HP3] ovaSource Renal enilon 7.5
Liquid (caramel) 125 ml		4 OP		enilon 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 - S		SA1377 abov	e – Hospital pharmacy [HP3]
Liquid, 1,000 ml bottle		1 OP	Vital
ORAL ELEMENTAL FEED 0.8KCAL/ML – Special Authority s Liquid (grapefruit), 250 ml carton Liquid (pineapple & orange), 250 ml carton Liquid (summer fruits), 250 ml carton	179.46 179.46	Hospital phar 18 OP 18 OP 18 OP 18 OP	macy [HP3] ✓ Elemental 028 Extra ✓ Elemental 028 Extra ✓ Elemental 028 Extra
ORAL ELEMENTAL FEED 1KCAL/ML – Special Authority se		ospital pharm	acy [HP3]
Powder (unflavoured), 80 g sachet		1 OP	✓ Vivonex TEN
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML – Special A Liquid, 500 ml bottle		above – Hosp 1 OP	ital pharmacy [HP3] ✓ Nutrison Advanced Peptisorb

# 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:

continued...

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

- 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 on the previous page – Hospital pharmacy [HP3]

Liquid, 500 ml bottle6.27	1 OP	Nutrini Low Energy
		Multi Fibre

## **Standard Supplements**

### ⇒SA1859 Special Authority for Subsidy

Initial application — (Children - indications other than exclusive enteral nutrition for Crohn's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 Any of the following:
  - 2.1 The patient has a condition causing malabsorption; or
  - 2.2 The patient has failure to thrive; or
  - 2.3 The patient has increased nutritional requirements; and
- 3 Nutrition goal has been set (eg reach a specific weight or BMI).

Renewal — (Children - indications other than exclusive enteral nutrition for Crohn's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 A nutrition goal has been set (eg reach a specific weight or BMI).

Initial application — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist or dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria: All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 Dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

**Renewal** — (Children - exclusive enteral nutrition for Crohn's disease) from any relevant practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria: 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.

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

Initial application — (Adults) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- Any of the following:
  - Patient is Malnourished
  - 1.1 Patient has a body mass index (BMI) of less than 18.5 kg/m<sup>2</sup>; or
  - 1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
  - Patient has a BMI of less than 20 kg/m<sup>2</sup> 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/m<sup>2</sup>; 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/m<sup>2</sup> 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</p>
    - 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.

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

continued...

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

- 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</p>
    - 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/mm<sup>3</sup>); 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.

ENTERAL FEED 1.5KCAL/ML - Special Authority see SA1859	on page 292 - Ho	spital pharma	acy [HP3]
Liquid, 1,000 ml bottle	8.68	1 OP	<ul> <li>Ensure Plus HN RTH</li> </ul>
	9.00		Nutrison Energy
Liquid, 250 ml can	2.17	1 OP	<ul> <li>Ensure Plus HN</li> </ul>
ENTERAL FEED 1KCAL/ML - Special Authority see SA1859 or	n page 292 – Hosp	oital pharmac	y [HP3]
Liquid, 1,000 ml bottle	6.56	1 OP	<ul> <li>Osmolite RTH</li> </ul>
	6.90		<ul> <li>Nutrison RTH</li> </ul>

# SPECIAL FOODS

	Outratate		-	
	Subsidy (Manufacturer's Pr		,	id or
	(Manulaciulei S Fi	Per Subsid		ufacturer
	,			
ENTERAL FEED WITH FIBRE 0.83 KCAL/ML - Special Authorit		1 page 292 – Ho 1 OP		
Liquid, 1,000 ml bottle	9.05	TOP	✓ Nutrise	
				Complete Fibre
ENTERAL FEED WITH FIBRE 1 KCAL/ML – Special Authority s				
Liquid, 1,000 ml bottle		1 OP	<ul> <li>Jevity</li> </ul>	
	7.21		<ul> <li>Nutrise</li> </ul>	on Multi Fibre
ENTERAL FEED WITH FIBRE 1.2KCAL/ML - Special Authority	see SA1859 on p	bage 292 – Hosp	ital pharma	icy [HP3]
Liquid, 1,000 ml bottle		1 OP	<ul> <li>Jevity</li> </ul>	Plus RTH
(Jevity Plus RTH Liquid, 1,000 ml bottle to be delisted 1 Septemb	oer 2025)			
ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority	see SA1859 on r	age 292 - Host	ital pharma	icv [HP3]
Liquid, 1,000 ml bottle		1 OP		HiCal RTH
				on Energy
				Fibre
ORAL FEED (POWDER) - Special Authority see SA1859 on page	no 202 - Hosnita	I nharmary [HP?	1	
Powder (chocolate)		840 g OP	-	en Hospital
		040 9 01	Form	
	26.00	850 g OP	✓ Ensure	
Powder (vanilla)		840 g OP		, Jen Hospital
Fowder (Varinia)		040 y OF		nula Active
	26.00	950 a OD	✓ Ensure	
		850 g OP		;
ORAL FEED 1.5KCAL/ML – Special Authority see SA1859 on pa	• I			
Additional subsidy by endorsement is available for patients b				
epidermolysis bullosa, or as exclusive enteral nutrition for the				
hypercapnia, defined as CO2 value exceeding 55mmHg. Th		ust be endorsed	accordingly	<i>.</i>
Liquid (banana), 200 ml bottle - Higher subsidy of up to \$1.7				
per 1 btl with Endorsement		1 OP	_	
	(1.56)		Ensure	
	(1.76)		Fortisip	)
Liquid (chocolate), 200 ml bottle – Higher subsidy of up to				
\$1.76 per 1 btl with Endorsement		1 OP		
	(1.56)		Ensure	
	(1.76)		Fortisip	1
Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of				
\$1.56 per 1 btl with Endorsement		1 OP		
	(1.56)		Ensure	Plus
Liquid (strawberry), 200 ml bottle – Higher subsidy of \$1.76				
1 btl with Endorsement	0.72	1 OP		
	(1.76)		Fortisip	)
Liquid (vanilla), 200 ml bottle – Higher subsidy of up to \$1.76				
per 1 btl with Endorsement	0.72	1 OP		
	(1.56)		Ensure	
	(1.76)		Fortisip	)
Liquid (vanilla), 237 ml can – Higher subsidy of \$1.65 per				
1 can with Endorsement	0.85	1 OP		
	(1.65)		Ensure	Plus

	Subsidy (Manufacturer's Price \$	) Su Per	Fully ubsidised	Brand or Generic Manufacturer
ORAL FEED WITH FIBRE 1.5 KCAL/ML – Special Authority see Additional subsidy by endorsement is available for patients b epidermolysis bullosa. The prescription must be endorsed a Liquid (chocolate), 200 ml bottle – Higher subsidy of \$1.76 p	eing bolus fed throu ccordingly.			
1 btl with Endorsement		1 OP	F	ortisip Multi Fibre
Liquid (strawberry), 200 ml bottle - Higher subsidy of \$1.76				
1 btl with Endorsement	0.72 (1.76)	1 OP	F	ortisip Multi Fibre
Liquid (vanilla), 200 ml bottle – Higher subsidy of \$1.76 per 1 btl with Endorsement	0.72	1 OP		
	(1.76)		F	ortisip 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.

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.

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer \$ ENTERAL FEED 2 KCAL/ML - Special Authority see SA1195 on the previous page -Hospital pharmacy [HP3] 1 OP Ensure Two Cal HN RTH 1 OP Nutrison Concentrated 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), 200 ml bottle - Higher subsidy of \$2.34 per 1 OP Two Cal HN (2.34)

# **Food Thickeners**

### ■ SA1106 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 vear 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.

FOOD THICKENER	- Special Authority see SA1106 above - Hospital pharma	cy [HP3]	
Powder		300 g OP	<ul> <li>Nutilis</li> </ul>
	24.00	380 g OP	<ul> <li>Aptamil Feed</li> </ul>
			Thickener

# Gluten Free Foods

The funding of gluten free foods is no longer being actively managed by Pharmac from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten free options are available through retail outlets.

### ■ SA1729 Special Authority for Subsidy

Initial application — (all patients) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria: Either:

- 1 Gluten enteropathy has been diagnosed by biopsy; or
- 2 Patient suffers from dermatitis herpetiformis.

Initial application — (paediatric patients diagnosed by ESPGHAN criteria) only from a paediatric gastroenterologist. Approvals valid without further renewal unless notified where the paediatric patient fulfils ESPGHAN criteria for biopsy free diagnosis of coeliac disease.

GLUTEN FREE BAKING MIX - Special Authority see SA1729 above - Hospita	l pharmacy [HP3]
Powder2.81	1,000 g OP
(5.15)	-

SPECIAL FOODS

. Thickener

Healtheries Simple **Baking Mix** 

	Subsidy (Manufacturer's P \$		Fully lised	Brand or Generic Manufacturer
GLUTEN FREE BREAD MIX - Special Authority see SA1729 on	the previous pa	<mark>ge</mark> – Hospital ph	armac	y [HP3]
Powder	3.93	1,000 g OP		
	(7.32)	-	N	ZB Low Gluten
				Bread Mix
	3.51			
	(10.87)		Н	orleys Bread Mix
GLUTEN FREE FLOUR – Special Authority see SA1729 on the Powder		Hospital pharma 2.000 g OP	icy [HI	P3]
	(18.10)	,	Н	orleys Flour

# Foods And Supplements For Inherited Metabolic Disease

### ⇒SA2357 Special Authority for Subsidy

**Initial application** from any relevant practitioner. Approvals valid without further renewal unless notified where patient requires dietary management of inherited metabolic disorders.

## **Supplements For Homocystinuria**

AMINOACID FORMULA WITHOUT METHIONINE	- Special Authority see SA2357	′ above – H	ospital pharmacy [HP3]
Powder (neutral), 36 g sachets		30	<ul> <li>HCU Anamix Junior</li> </ul>
Powder, 12.5 g sachets		30	HCU Explore 5
Powder, 25 g sachets	1,048.95	30	<ul> <li>HCU Express 15</li> </ul>
Powder (neutral), can		500 g OP	<ul> <li>XMET Maxamum</li> </ul>
Powder (unflavoured), can		400 g OP	<ul> <li>HCU Anamix Infant</li> </ul>
Liquid (juicy berries), 125 ml bottle	1,684.80	30	HCU Lophlex LQ
Liquid (orange), 125 ml bottle	941.40	36	<ul> <li>HCU Anamix Junior</li> </ul>
			LQ

# Supplements For MSUD and short chain enoyl coA hydratase deficiency

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE – Special Authority see SA2357 above – Hospital pharmacy [HP3]

Powder (neutral) 36 g sachets	30	Junior
Powder, 12.5 g sachets	30	MSUD Explore 5
Powder, 25 g sachets 1,048.95	30	MSUD Express 15
Powder (neutral), can454.71	500 g OP	<ul> <li>MSUD Maxamum</li> </ul>
Powder (orange), can454.71	500 g OP	MSUD Maxamum
Powder (unflavoured), can	400 g OP	<ul> <li>MSUD Anamix Infant</li> </ul>
Liquid (orange) 125 ml bottles	36	<ul> <li>MSUD Anamix Junior LQ</li> </ul>
Liquid (juicy berries) 125 ml pouches 1,684.80	30	<ul> <li>MSUD Lophlex LQ 20</li> </ul>

	Subsidy (Manufacturer's Prio \$	ce) Suba Per	Fully sidised	Brand or Generic Manufacturer
Supplements For PKU				
/INOACID FORMULA WITHOUT PHENYLALANINE - S	pecial Authority see SA	2357 on the	previou	s page – Hospital
armacy [HP3]	00.00	75.00		1. I
Tabs		75 OP		hlexy 10
Powder (Lemon), 34 g sachets		30		KU Express 20
Powder (Neutral), 12.5 g sachets		30		KU Explore 5
Powder (Neutral), 34 g sachets		30		KU Express 20
Powder (Orange), 25 g sachets		30		KU Explore 10
Powder (Orange), 34 g sachets		30		KU Express 20
Powder (Raspberry), 25 g sachets		30		KU Explore 10
Powder (Tropical), 34 g sachets		30		KU Express 20
Powder (berry) 28 g sachets	936.00	30	✓ P	KU Lophlex Powder
Powder (chocolate) 36 g sachet		30	✓ P	KU Anamix Junior Chocolate
Powder (neutral) 28 g sachets	936.00	30	✓ P	KU Lophlex Powder
Powder (neutral) 36 g sachets	303 00	30	<b>/</b> P	KU Anamix Junio
Powder (orange) 28 g sachets		30		KU Lophlex
		50	• •	Powder
Powder (orange) 36 g sachet		30	✓ P	KU Anamix Junio
				Orange
Powder (unflavoured) 12.5 g sachets		30		KU First Spoon
Powder (vanilla) 36 g sachet		30	✓ P	KU Anamix Junio Vanilla
Infant formula	174.72	400 g OP	🗸 P	KU Anamix Infant
Powder (neutral), 4 × 400 g can	715.16	1,600 g OP	🗸 P	ku Start
Powder (orange)		500 g OP	✓ X	P Maxamum
Powder (unflavoured)		500 g OP	✓ X	P Maxamum
Liquid (berry), 125 ml bottle	13.10	1 OP	✓ P	KU Anamix Junio
Liquid (orange), 125 ml bottle	13.10	1 OP	✓ P	KU Anamix Junio
Liquid (forest berries), 250 ml carton	540.00	18 OP	<b>./</b> =	asiphen Liquid
Liquid (juicy tropical) 125 ml.		30 OP		KU Lophlex LQ 20
Oral semi-solid (berries) 109 g		36 OP		KU Lophlex
Oral seriir-solid (Derries) 108 g	1,123.20	30 UF	₹ P	Sensation 20
Liquid (juicy berries) 62.5 ml	939.00	60 OP	✓ P	KU Lophlex LQ 10
Liquid (juicy berries) 125 ml		30 OP	V P	KU Lophlex LQ 20
Liquid (juicy orange) 125 ml		30 OP		KU Lophlex LQ 20

SPECIAL FOODS

	Subsidy		Fully Brand or
	(Manufacturer's Price) \$	Per	Subsidised Generic Manufacturer
YCOMACROPEPTIDE AND AMINO ACID CONTAINS SC	OME PHENYLALANINE	– Spe	ecial Authority see SA2357 on
ge 298 – Hospital pharmacy [HP3]			
Powder (Banana) 35 g sachets		30	🗸 PKU
			sphere20 Banana
Powder (Berry), 20 g sachets		60	<ul> <li>PKU Restore</li> </ul>
			Powder
Powder (Chocolate) 32 g sachets		30	🗸 PKU Build
			20 Chocolate
Powder (Chocolate) 35 g sachets		30	🖌 PKU
( , , ,			sphere20 Chocolate
Powder (Lemon) 35 g sachets		30	✓ PKU
			sphere20 Lemon
Powder (Lemonade) 33.4 g sachets		30	PKU GMPro Ultra
			Lemonade
Powder (Neutral), 15 g sachets		30	PKU Build 10
Powder (Orange), 20 g sachets		60	PKU Restore
			Powder
Powder (Raspberry Lemonade) 31 g sachets		30	🗸 PKU Build
			20 Raspberry
			Lemonade
Powder (Smooth) 31 g sachets	898.56	30	✓ PKU Build
		00	20 Smooth
Powder (Vanilla) 33 g sachets	898 56	30	✓ PKU Build 20 Vanilla
Powder (neutral), 40 g sachets		30	✓ Glytactin Bettermilk
Powder (unflavoured) 12.5 g sachets		30	✓ PKU GMPro Mix-In
Powder (vanilla) 33.4 g sachets		30	✓ PKU GMPro Ultra
		00	Vanilla
Powder (Red Berry) 35 g sachets	930.00	30	✓ PKU sphere20 Red
		00	Berry
Powder (Vanilla) 35 g sachets	930 00	30	✓ PKU
		00	sphere20 Vanilla
Liquid (neutral), 250 ml carton	280.80	18	✓ PKU GMPro LQ
Liquid (riginal), 250 ml carton		30 OF	
		00 Or	15
Liquid (Coffee Mocha), 250 ml carton		30 OF	P Y PKU Glytactin RTD
			15 Lite
Liquid (chocolate), 250 ml carton		30 OF	P Y PKU Glytactin RTD
( ( (-), <b>_</b> (			15
Liquid (vanilla), 250 ml carton	684 45	30 OF	
		20 01	15 Lite

# Foods

LOW PROTEIN BAKING MIX - Special Authority see SA2357 c	n page 298 – Ho	spital pharmacy	/ [HP3]
Powder	8.55	500 g OP	<ul> <li>Loprofin Mix</li> </ul>

# SPECIAL FOODS

	Subsidy		Fully Brand or
	(Manufacturer's Pr	ice) Subs	idised Generic
	\$	Per	<ul> <li>Manufacturer</li> </ul>
LOW PROTEIN RASTA Special Authority and SA2257 on page	o 200 Hoopital r	hormooy [UD!	01
LOW PROTEIN PASTA – Special Authority see SA2357 on page			
Animal shapes		500 g OP	<ul> <li>Loprofin</li> </ul>
Lasagne	6.19	250 g OP	<ul> <li>Loprofin</li> </ul>
Low protein rice pasta		500 g OP	<ul> <li>Loprofin</li> </ul>
Macaroni	6 19	250 g OP	<ul> <li>Loprofin</li> </ul>
Penne		500 g OP	✓ Loprofin
		500 g OP	✓ Loprofin
Spaghetti			
Spirals		500 g OP	<ul> <li>Loprofin</li> </ul>
Supplements for Tyrosinaemia			
			- CA0057 000
AMINOACID FORMULA WITHOUT PHENYLALANINE AND TYP	RUSINE - Specia	al Authority see	e SA2357 on page 298 - Hospit
pharmacy [HP3]			
Powder (Neutral), 12.5 g sachets		30	<ul> <li>TYR Explore 5</li> </ul>
Powder (neutral) 36 g sachets	471.00	30	<ul> <li>TYR Anamix Junior</li> </ul>
Powder, can		400 g OP	<ul> <li>TYR Anamix Infant</li> </ul>
Liquid (juicy berries) 125 ml pouches		30	<ul> <li>TYR Lophlex LQ 20</li> </ul>
		36	✓ TYR Anamix Junior
Liquid (orange) 125 ml bottle		30	LQ
GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOME	TYROSINE AND	) PHENYLALA	ANINE – Special Authority see
SA2357 on page 298 – Hospital pharmacy [HP3]			
Powder (Red Berry), 35 g sachets	1 398 60	30	<ul> <li>TYR Sphere 20</li> </ul>
Powder (Vanilla), 35 g sachets	1 200 60	30	✓ TYR Sphere 20
Powder (Varilia), 55 y sacriets	1,390.00	30	<ul> <li>The Sphere 20</li> </ul>
Supplements for Organic Acidaemias			
AMINOACID FORMULA WITHOUT ISOLEUCINE, METHIONINE	E, THREONINE A	ND VALINE -	- Special Authority see SA2357
on page 298 – Hospital pharmacy [HP3]	·		, ,
Powder, can		400 g OP	MMA/PA Anamix
		-	Infant
AMINOACID FORMULA WITHOUT METHIONINE, THREONINE		Special Autho	
	AND VALINE -	Special Autrio	my see 3A2337 on page 296 -
Hospital pharmacy [HP3]			_
Powder (neutral), 18 g sachets	750.30	30	MMA/PA Anamix
			Junior
Powder, 12.5 g sachets	349 65	30	MMA/PA Explore 5
		30	<ul> <li>MMA/PA Express 15</li> </ul>
Powder, 25 g sachets	1,040.95	30	WIMA/PA Express 15
O mail and the Older is Astronomy d			
Supplements for Glutaric Aciduria type 1			
	0 4 0 0 5 7		anital alconnector [UID0]
AMINOACID FORMULA WITHOUT LYSINE - Special Authority		-	
Powder (neutral), 18 g sachets	750.30	30	<ul> <li>GA1 Anamix Junior</li> </ul>
Powder, 12.5 g sachets		30	GA Explore 5
Powder, can	260.00	400 g OP	<ul> <li>GA1 Anamix Infant</li> </ul>
	200100		
Supplements for Glycogen Storage Disease			
	CA0257 on north		h phormooy [HD2]
HIGH AMYLOPECTIN CORN-STARCH - Special Authority see		•	
Powder, 60 g sachets	241.62	30	<ul> <li>Glycosade</li> </ul>
Single dose amino acids			
	the Lack company of the	201	
ARGININE – Special Authority see SA2357 on page 298 – Hosp		-	<b>.</b>
Powder, 4 g sachets	211.45	30	<ul> <li>Arginine2000</li> </ul>

	Per	<ul> <li>Manufacturer</li> </ul>
pital pharmacy [HI 211.45	P3] 30	✓ Citrulline1000
	P3] 30	✓ Isoleucine50
	30	✓ Leucine100
	cy [HP3] 30	✓ Phenylalanine50
211.45	3] 30	✓ Tyrosine1000
<i>.</i>	30	✓ Valine50
ES - Special Auth	hority see SA2	2357 on page 298 – Hospital
47.01	10	<ul> <li>Emsogen</li> </ul>
ninerals		
	400 g OP	<ul> <li>Energivit</li> </ul>
		armacy [HP3] <b>✓ Essential Amino</b> Acid Mix
	spital pharmacy [H 141.05 I pharmacy [HP3] 141.05 - Hospital pharma 141.05 tal pharmacy [HP3] 211.45 oharmacy [HP3] 141.05 ES – Special Auti 47.01 <b>ninerals</b> E, FAT WITH ADD 49.29	spital pharmacy [HP3] 141.05 30 Il pharmacy [HP3] 141.05 30 - Hospital pharmacy [HP3] 141.05 30 tal pharmacy [HP3] 211.45 30 oharmacy [HP3] 141.05 30 ES – Special Authority see SA2 47.01 10 <b>ninerals</b> E, FAT WITH ADDED VITAMINS 49.29 400 g OP

## For Williams Syndrome

### ⇒SA1110 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is an infant suffering from Williams Syndrome and associated hypercalcaemia.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

LOW CALCIUM INFANT FORMULA	- Special Authority see SA1110	above – Hospital pharmacy [HP3]
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Powder	400 g OP	<ul> <li>Locasol</li> </ul>
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	Subsidy		Fully	Brand or
	(Manufacturer's F	Price) Sub	sidised	Generic
	\$	Per	1	Manufacturer
Gastrointestinal and Other Malabsorptive Prob	lems			
AMINO ACID FORMULA - Special Authority see SA2092 below	– Hospital pharr	macy [HP3]		
Powder		400 g OP	🗸 🖌	Alfamino
		Ū	✓ #	Alfamino Junior
Powder (unflavoured)		400 g OP	🗸 N	leocate Gold
		-	✓ N	leocate Junior Unflavoured
			🗸 N	leocate SYNEO
	65.72		🖌 E	Elecare
			✓ E	Elecare LCP
Powder (vanilla)	55.61	400 g OP	✓ N	leocate Junior Vanilla
	65.72		✓ E	lecare

### ► 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 immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 Either:
  - 1.1 Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist; or
  - 1.2 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient; and
- 2 Any of the following:
  - 2.1 History of anaphylaxis to cow's milk protein formula or dairy products; or
  - 2.2 Eosinophilic oesophagitis; or
  - 2.3 Ultra-short gut; or
  - 2.4 Severe Immune deficiency; or
  - 2.5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
  - 2.6 Both:
    - 2.6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and
    - 2.6.2 Either:
      - 2.6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval

continued...

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

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
- 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:

continued...

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

continued...

All of the following:

- 1 Patient has a valid Special Authority approval for extensively hydrolysed formula (SA1557); and
- 2 Extensively hydrolysed formula (Aptamil Gold+ Pepti Junior, AllerPro SYNEO 1 and 2) is unable to be supplied at this time; and
- 3 The approval only applies to funded dispensings of Neocate Gold and Neocate Syneo.

Note: This criteria is short term funding to cover an out-of-stock situation on some extensively hydrolysed formula powder funded under Special Authority form SA1557. There is no renewal criteria under this restriction.

ENTERAL LIQUID PEPTIDE FORMULA	- Special Authority see SA1953 below	- Hospital ph	armacy [HP3]
Liquid 1 kool/ml 500 ml bottlo	10 //	1 00	🖌 Nutrini Don

Liquid 1 kcai/mi, 500 mi bottie	I OP	<ul> <li>Nutrini Peptisorb</li> </ul>
Liquid 1.5 kcal/ml, 500 ml bottle	1 OP	<ul> <li>Nutrini Peptisorb</li> </ul>
		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
    - 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 on t	he next page -	Hospital pharmacy [HP3]
Powder		450 g OP	<ul> <li>Pepti-Junior</li> </ul>
	36.20	900 g OP	<ul> <li>Allerpro Syneo 1</li> </ul>
			Allerpro Syneo 2

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

## ⇒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.

**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, 125 ml bottle		1 OP	<ul> <li>Infatrini</li> </ul>

#### ⇒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.

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

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 – Hospit	al pharmacy [HP3]
Powder (unflavoured)	36.92	300 g OP	<ul> <li>KetoCal 4:1</li> </ul>
		-	Ketocal 3:1
Powder (vanilla)	36.92	300 g OP	<ul> <li>KetoCal 4:1</li> </ul>

# SECTION I: NATIONAL IMMUNISATION SCHEDULE

	Subsidy (Manufacturer's Price) \$	) Su Per	Fully bsidised	Brand or Generic Manufacturer
Vaccinations				
ACILLUS CALMETTE-GUERIN VACCINE – [Xpharm]				
For infants at increased risk of tuberculosis. Increased risk				
1) living in a house or family with a person with current				
<ol> <li>having one or more household members or carers v equal to 40 per 100,000 for 6 months or longer; or</li> </ol>	who within the last 5 yea	irs lived i	n a count	ry with a rate of TB > or
<ol> <li>during their first 5 years will be living 3 months or longer, or</li> </ol>	nger in a country with a	rate of T	B > or ea	ual to 40 per 100.000
Note a list of countries with high rates of TB are available				
www.bcgatlas.org/index.php.	Ũ			,
Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin)				
Danish strain 1331, live attenuated, vial with diluent.	0.00	10	✓ E	3CG Vaccine AJV
OVID-19 VACCINE - [Xpharm]				
Inj 3 mcg bretovameran per 0.3 ml, 0.48 ml vial; infant va vellow cap		10	10	Comirnaty Omicron
	0.00	10	• •	(JN.1)
Up to three doses for previously unvaccinated childre	en aged 6 months - 4 ye	ars at hig	h risk of	severe illness.
Inj 10 mcg bretovameran per 0.3 ml, 0.48 ml vial; paediat	ric			
vaccine, light blue cap		10	✓ (	Comirnaty Omicron (JN.1)
Either:				
<ol> <li>One dose for previously unvaccinated children a</li> <li>Up to three doses for immunocompromised children a</li> </ol>				
Inj 30 mcg bretovameran per 0.3 ml, 0.48 ml vial; adult va	ccine.			
light grey cap		10	✓ (	Comirnaty Omicron
Anne of the fellowing				(JN.1)
Any of the following:				
<ol> <li>One dose for previously unvaccinated people a</li> <li>Up to three doses for immunocompromised people</li> </ol>	• •	ld <sup>.</sup> or		
<ul><li>3) Up to two doses for previously unvaccinated per</li></ul>				
4) Up to four doses for people aged 16-29 at high	risk of severe illness; or			
<ol> <li>One dose for previously unvaccinated people a</li> <li>One additional dose every 6 months for previou</li> </ol>		1.00		

6) One additional dose every 6 months for previously vaccinated people aged 30 years and over – additional dose is given at least 6 months after last dose.

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

#### DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- C)
- A) Funded for any of the following criteria:
  - 1) A single dose for pregnant women in the second or third trimester of each pregnancy; or
  - 2) A single dose for parents or primary caregivers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days, who had not been exposed to maternal vaccination at least 14 days prior to birth; or
  - A course of up to four doses is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
  - 4) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
  - 5) A single dose for vaccination of patients aged from 65 years old; or
  - 6) A single dose for vaccination of patients aged from 45 years old who have not had 4 previous tetanus doses; or
  - 7) For vaccination of previously unimmunised or partially immunised patients; or
  - 8) For revaccination following immunosuppression; or
  - 9) For boosting of patients with tetanus-prone wounds.
  - Notes: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.
- B) Contractors will be entitled to claim payment from the Funder for the supply of diphtheria, tetanus and pertussis vaccine to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the diphtheria, tetanus and pertussis vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs 1 – 9 above.
- Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg

pertussis toxoid, 8 mcg pertussis filamentous haemaodutinin and 2.5 mcg pertactin in 0.5 ml prefilled

maemaggiutinin and 2.5 mcg pertactin in 0.5 mi premied			
syringe	0.00	10	<ul> <li>Boostrix</li> </ul>

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

10

Infanrix IPV

#### DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE

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

A) Funded for any of the following:

- 1) A single dose for children up to the age of 7 who have completed primary immunisation; or
- 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 people post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
- 4) Five doses will be funded for children requiring solid organ transplantation.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Diphtheria, tetanus, pertussis and polio vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Diphtheria, tetanus, pertussis and polio vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

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

Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg

pertussis toxoid, 25 mcg pertussis filamentous

haemagglutinin, 8 mcg pertactin and 80 D-antigen units

poliomyelitis virus in 0.5ml syringe ......0.00

DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE

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

C)

- A) Funded for children meeting any of the following criteria
  - 1) Up to four doses for children under the age of 10 years for primary immunisation; or
  - An additional four doses (as appropriate) for (re-)immunisation of children under the age of 18 years post haematopoietic stem cell transplantation; or
  - 3) An additional four doses (as appropriate) for (re-)immunisation of children under the age of 10 years who are post chemotherapy; pre or post splenectomy; undergoing renal dialysis and other severely immunosuppressive regimens; or
  - 4) Up to five doses for children under the age of 10 years receiving solid organ transplantation.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type b vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type b vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Inj 30IU diphtheria with 40IU tetanus and 25mcg pertussis toxoids, 25mcg pertussis filamentous haemagglutinin, 8mcg pertactin, 80D-AgU polio virus, 10mcg hepatitis B antigen, 10mcg H. influenzae type b with tetanus toxoid 20-40mcg in 0.5ml syringe .......0.00

10



Subsidy (Manufacturer's Price)	Full Subsidise		
\$	Per 🖌	Manufacturer	

#### HAEMOPHILUS INFLUENZAE TYPE B VACCINE

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

A) One dose for people meeting any of the following:

- 1) For primary vaccination in children; or
- 2) An additional dose (as appropriate) is funded for (re-)immunisation for people post haematopoietic stem cell transplantation, or chemotherapy; functional asplenic; pre or post splenectomy; pre- or post solid organ transplant, pre or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or
- For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Haemophilus influenzae type b vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Haemophilus influenzae type b vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for 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 10 mcg vial with diluent syringe0.00	1	✓ <u>Act-HIB</u>
HEPATITIS A VACCINE – [Xpharm]		
Funded for patients meeting any of the following criteria:		
<ol> <li>Two vaccinations for use in transplant patients; or</li> </ol>		
<ol><li>Two vaccinations for use in children with chronic liver disease; or</li></ol>		
<ol><li>One dose of vaccine for close contacts of known hepatitis A cases.</li></ol>		
Lei dato El IOA velha in duel evoluer		<b>(</b> )
Inj 1440 ELISA units in 1 ml syringe0.00	1	<ul> <li><u>Havrix 1440</u></li> </ul>
Inj 720 ELISA units in 0.5 ml syringe0.00	1	✓ <u>Havrix Junior</u>

		Subsidy (Manufacturer's Price) \$	Sub Per	Fully sidised	Brand or Generic Manufacturer
HEPATITIS E	RECOMBINANT VACCINE - [Xpharm]				
lnj 10 mc	g per 0.5 ml prefilled syringe	0.00	1	✓ <u>E</u>	ngerix-B
	led for patients meeting any of the following criteria:				
1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or					
	2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or				
3)	for children up to and under the age of 18 years inc				achieved a positive
	serology and require additional vaccination or requ	ire a primary course o	of vaccina	ition; or	
	for HIV positive patients; or				
	for hepatitis C positive patients; or for patients following non-consensual sexual interc				
,	for patients prior to planned immunosuppression for		e: or		
,	for patients following immunosuppression; or	i greater than 20 day	5, 01		
	for solid organ transplant patients; or				
	for post-haematopoietic stem cell transplant (HSC)	<ul><li>F) patients; or</li></ul>			
	following needle stick injury.				
lnj 20 mc	g per 1 ml prefilled syringe	0.00	1	✓ <u>E</u>	ngerix-B
Func	led for patients meeting any of the following criteria:				
	for household or sexual contacts of known acute he				s; or
	for children born to mothers who are hepatitis B su				
3)	for children up to and under the age of 18 years inc				achieved a positive
4)	serology and require additional vaccination or requ for HIV positive patients; or	ire a primary course o	or vaccina	tion; or	
	for hepatitis C positive patients; or				
,	for patients following non-consensual sexual interc	OUISE. OL			
,	for patients prior to planned immunosuppression for		s: or		
,	8) for patients following immunosuppression; or				
	9) for solid organ transplant patients; or				
10)	10) for post-haematopoietic stem cell transplant (HSCT) patients; or				
,	following needle stick injury; or				
,	for dialysis patients; or				
13)	for liver or kidney transplant patients.				

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

HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV]

- a) Maximum of 1 inj per prescription
- b) Only on a prescription
- c) No patient co-payment payable

d)

- a) A) Any of the following:
  - 1) Maximum of two doses for children aged 14 years and under; or
  - 2) Maximum of three doses for people meeting any of the following criteria:
    - 1) People aged 15 to 26 years inclusive; or
    - 2) Either:
      - People aged 9 to 26 years inclusive who have
        - 1) Confirmed HIV infection; or
        - 2) Received a transplant (including stem cell): or
  - 3) Maximum of four doses for people aged 9 to 26 years inclusive post chemotherapy
  - B) Contractors will be entitled to claim payment from the Funder for the supply of Human papillomavirus vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Human papillomavirus vaccine listed in the Pharmaceutical Schedule.
  - C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs A above.

Inj 270 mcg in 0.5 ml syringe	0.00	10	<ul> <li>Gardasil 9</li> </ul>
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
INFLUENZA VACCINE Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)		10	🗸 Ir	nfluvac Tetra (2025 formulation)

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

- a) Maximum of 1 inj per prescription
- b) Only on a prescription
- c) No patient co-payment payable
- d)

### A) INFLUENZA VACCINE

is available each year for patients 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 4 years of age and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness; or
- d) people under 65 years of age who:
  - i) have any of the following serious mental health conditions:
    - a) schizophrenia, or
    - b) major depressive disorder, or
    - c) bipolar disorder, or
    - d) schizoaffective disorder, or
  - ii) are currently accessing secondary or tertiary mental health and addiction services; or

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Contractors will be entitled to claim payment for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with Health NZ for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

S Per 🖌 Manufacturer
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### MEASLES, MUMPS AND RUBELLA 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 for the supply of measles, mumps and rubella vaccine to patients eligible under the above criteria pursuant to their contract with Health NZ for subsidised immunisation, and they may only do so in respect of the measles, mumps and rubella vaccine listed in the Pharmaceutical Schedule.
- 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 diluent 0.5 ml
 10

Priorix

	Subsidy	Fully	y Brand or
	(Manufacturer's Price) \$	Subsidised	
MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJU			inanalaotaroi
Inj 10 mcg of each meningococcal polysaccharide conju	gated		
to a total of approximately 55 mcg of tetanus toxoid			
per 0.5 ml vial	0.00	1 🗸	MenQuadfi
a) Only on a prescription			
<ul> <li>b) No patient co-payment payable</li> </ul>			
<ul><li>c)</li><li>A) Any of the following:</li></ul>			
1) Up to three doses and a booster ever	y five years for patients p	re- and post sp	lenectomy and for patients
with functional or anatomic asplenia,			
solid organ transplant; or			
<ol> <li>One dose for close contacts of menin</li> </ol>			
<ol> <li>One dose for person who has previou</li> <li>A maximum of two doses for here and</li> </ol>	, ,	, ,	roup; or
<ol> <li>A maximum of two doses for bone ma</li> <li>A maximum of two doses for person p</li> </ol>			
B) Both:	ne- and post-inimunosup	016331011, 01	
1) Person is aged between 13 and 25 ye	ears, inclusive; and		
2) Either:			
<ol> <li>One dose for individuals who ar</li> </ol>			
in boarding school hostels, tertia	ary education halls of resid	dence, military	barracks, Youth Justice
residences, or prisons; or 2) One dose for individuals who tu	rn 12 years of ago while li	vina in boardin	a sobool bostole
C) Contractors will be entitled to claim payment	, ,	•	•
W-135 vaccine to patients eligible under the			
(Health NZ) for subsidised immunisation, a			
W-135 vaccine listed in the Pharmaceutica			
<ul> <li>D) Contractors may only claim for patient population</li> </ul>			ed by their contract, which
may be a sub-set of the population describ Note: children under seven years of age require			a three years after the
primary series and then five yearly.	two uoses o weeks apair	, a booster uos	e intee years after the
*Immunosuppression due to steroid or other imm	unosuppressive therapy i	must be for a p	eriod of greater than
28 days.			Ū
Inj 5 mcg of each meningococcal polysaccharide conjug			
a total of approximately 44 mcg of tetanus toxoid ca			
per 0.5 ml vial – [Xpharm]	0.00	1 🗸	Nimenrix
A) Both:			
<ol> <li>The child is under 12 months of age; and</li> <li>Any of the following:</li> </ol>			
1) A maximum of three doses (depend	lant on age at first dose) f	or natients nre	- and nost- splenectomy and
for patients with functional or anato			
pre- or post- solid organ transplant;			, (,
2) A maximum of three doses (depend		or close contac	cts of meningococcal cases
of any group; or			
<ol> <li>A maximum of three doses (depend maningaccoord diagona of any gray</li> </ol>		or child who ha	as previously had
meningococcal disease of any grou 4) A maximum of three doses (dependent		or hone marro	w transplant patients: or
4) A maximum of three doses (depend 5) A maximum of three doses (depend			

5) A maximum of three doses (dependant on age at first dose) for child pre- and post-immunosuppression\*.

Note: infants from 6 weeks to less than 6 months of age require a 2+1 schedule, infants from 6 months to less than 12 months of age require a 1+1 schedule. Refer to the Immunisation Handbook for recommended booster schedules with meningococcal ACWY vaccine.

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

### MENINGOCOCCAL B MULTICOMPONENT VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c) Any of the following:
  - A) Three doses for children up to 12 months of age (inclusive) for primary immunisation; or
  - B) Up to three doses (dependent on age at first dose) for a catch-up programme for children from 13 months to
    - 59 months of age (inclusive) for primary immunisation, from 1 March 2023 to 31 August 2025; or
  - C) 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\*; or
  - D) Both:
    - 1) Person is aged between 13 and 25 years (inclusive); and
    - 2) Either:
      - Two doses 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, Youth Justice residences or prisons; or
      - ii) Two doses for individuals who turn 13 years of age while living in boarding school hostels.
  - E) Contractors will be entitled to claim payment from the Funder for the supply of Meningococcal B multicomponent vaccine to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Meningococcal B multicomponent vaccine listed in the Pharmaceutical Schedule.
  - F) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs A-D above.

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

Inj 175 mcg per 0.5 ml prefilled syringe	0.00	1	<ul> <li>Bexsero</li> </ul>
		10	Bexsero

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

#### PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE

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

A) Any of the following:

- 1) A course of three doses for previously unvaccinated children up to the age of 59 months inclusive; or
- Two doses are funded for high risk individuals (over the age of 12 months and under 18 years) who have previously received two doses of the primary course of PCV10; or
- 3) Up to an additional four doses (as appropriate) are funded for the (re)immunisation of high risk children aged under 5 years 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) primary immune deficiencies; or
  - c) HIV infection; or
  - d) renal failure, or nephrotic syndrome; or
  - e) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
  - f) cochlear implants or intracranial shunts; or
  - g) cerebrospinal fluid leaks; or
  - 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) chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
  - j) pre term infants, born before 28 weeks gestation; or
  - k) cardiac disease, with cyanosis or failure; or
  - I) diabetes; or
  - m) Down syndrome; or
  - n) who are pre-or post-splenectomy, or with functional asplenia; or
- 4) Up to an additional four doses (as appropriate) are funded for the (re-)immunisation of individuals 5 years and over with HIV, 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
- 5) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Pneumococcal (PCV13) conjugate vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Pneumococcal (PCV13) conjugate vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes Inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4,

5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5ml	
syringe	0.00

10	✓	Prevenar 13
1	✓	Prevenar 13

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✔	Brand or Generic Manufacturer
PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE – Any of the following:	[Xpharm]		
<ol> <li>Up to three doses (as appropriate) for patients with H chemotherapy; pre- or post-splenectomy or with funct complement deficiency (acquired or inherited), cochle</li> <li>All of the following:</li> </ol>	ional asplenia, pre- or p	oost-solid organ t	ransplant, renal dialysis,
<ul><li>a) Patient is a child under 18 years for (re-)immuni</li><li>b) Treatment is for a maximum of two doses; and</li><li>c) Any of the following:</li></ul>	sation; and		
<ul> <li>i) on immunosuppressive therapy or radiatio immune response; or</li> <li>ii) with primary immune deficiencies; or</li> <li>iii) with HIV infection; or</li> </ul>	n therapy, vaccinate wh	en there is expe	cted to be a sufficient
<ul> <li>iv) with renal failure, or nephrotic syndrome; of</li> <li>v) who are immune-suppressed following orgor</li> <li>or</li> <li>vi) with cochlear implants or intracranial shundright</li> </ul>	an transplantation (incl	uding haematopo	pietic stem cell transplant);
<ul> <li>vii) with cerebrospinal fluid leaks; or</li> <li>viii) receiving corticosteroid therapy for more the prednisone of 2 mg/kg per day or greater, 20 mg or greater; or</li> </ul>	nan two weeks, and who		
<ul> <li>ix) with chronic pulmonary disease (including</li> <li>x) pre term infants, born before 28 weeks ge</li> <li>xi) with cardiac disease, with cyanosis or failu</li> <li>xii) with diabetes; or</li> </ul>	station; or	h-dose corticost	eroid therapy); or
xii) with diabetes, or xiii) with Down syndrome; or xiv) who are pre-or post-splenectomy, or with f	unctional asplenia; or		
<ol> <li>For use in testing for primary immunodeficiency disea paediatrician</li> </ol>	uses, on the recommend	dation of an interr	nal medicine physician or
Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	0.00	1 🖌 <u>P</u>	neumovax 23
POLIOMYELITIS VACCINE – [Xpharm] Up to three doses for patients meeting either of the followin 1) For partially vaccinated or previously unvaccinated in 2) For revaccination following immunosuppression.	•		
Note: Please refer to the Immunisation Handbook for appr Inj 80D antigen units in 0.5 ml syringe		ch-up programm 1 ✓ <u>II</u>	

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

### ROTAVIRUS ORAL VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Maximum of two doses for people 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.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Rotavirus oral vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Rotavirus oral vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Oral susp live attenuated human rotavirus		
1,000,000 CCID50 per dose, squeezable tube0.00	10	<ul> <li>Rotarix</li> </ul>
Oral susp live attenuated human rotavirus		
1,000,000 CCID50 per dose, squeezable tube (PVC free) 0.00	10	<ul> <li>Rotarix</li> </ul>
Oral susp live attenuated human rotavirus		
1,000,000 CCID50 per dose, prefilled oral applicator0.00	10	<ul> <li>Rotarix</li> </ul>

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

#### VARICELLA VACCINE [CHICKENPOX VACCINE]

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

c)

A) Either:

- 1) Maximum of one dose for primary vaccination for either:
  - a) Any infant born on or after 1 April 2016; or
  - b) For previously unvaccinated children turning 11 years old on or after 1 July 2017, who have not previously had a varicella infection (chickenpox), or
- 2) Maximum of two doses for any of the following:
  - a) Any of the following for non-immune individuals:
    - i) with chronic liver disease who may in future be candidates for transplantation; or
    - ii) with deteriorating renal function before transplantation; or
    - iii) prior to solid organ transplant; or
    - iv) prior to any elective immunosuppression\*; or
    - v) for post exposure prophylaxis who are immune competent inpatients; or
  - b) For individuals at least 2 years after bone marrow transplantation, on advice of their specialist; or
  - c) For individuals at least 6 months after completion of chemotherapy, on advice of their specialist; or
  - For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist; or
  - e) For individuals with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella; or
  - f) For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella; or
  - g) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Varicella vaccine [Chickenpox vaccine] vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Varicella vaccine [Chickenpox vaccine] listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs A above.

\* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

Subsidy		Fully	Brand or
(Manufacturer's Price)	9	Subsidised	Generic
\$	Per	1	Manufacturer

#### VARICELLA ZOSTER VACCINE [SHINGLES VACCINE]

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Funded for patients meeting the following criteria:
  - Either:
    - 1) Two doses for all people aged 65 years, or
    - 2) Two doses for people 18 years of age or older with any of the following:
      - a) pre- and post-haematopoietic stem cell transplant or cellular therapy; or
        - b) pre- or post-solid organ transplant; or
        - c) haematological malignancies; or
        - d) people living with poorly controlled HIV infection; or
        - e) planned or receiving disease modifying anti-rheumatic drugs (DMARDs targeted synthetic, biologic, or conventional synthetic) for polymyalgia rheumatica, systemic lupus erythematosus or rheumatoid arthritis; or
        - f) end stage kidney disease (CKD 4 or 5); or
        - g) primary immunodeficiency
- B) Contractors will be entitled to claim payment from the Funder for the supply of Varicella zoster vaccine (Shingles vaccine) to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Varicella zoster vaccine [Shingles 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.

Inj 50 mcg per 0.5 ml vial plus vial	0.00	1	<ul> <li>Shingrix</li> </ul>
		10	<ul> <li>Shingrix</li> </ul>

# **Diagnostic Agents**

TUBERCULIN PPD [MANTOUX] TEST - [Xpharm]			
Inj 5 TU per 0.1 ml, 1 ml vial	0.00	1	<ul> <li><u>Tubersol</u></li> </ul>

3TC114
- A -
A-Scabies
Abacavir sulphate 113
Abacavir sulphate with
lamivudine 113
Abacavir/Lamivudine Viatris
Abilify Maintena
Abiraterone acetate
Acarbose
Accarb
Acetazolamide
Acetec
Acetic acid with hydroxyquinoline and
Acetic acid with hydroxyquinoline and
ricinoleic acid
Acetylcysteine
Aci-Jel
Aciclovir
Infection109
Sensory276
Acidex6
Acipimox53
Acitretin72
Act-HIB
Actemra 239
Actinomycin D159
Actrapid10
Actrapid Penfill10
Acupan
Adalimumab (Amgevita)189
Adalimumab (Humira - Alternative
brand)
Adapalene67
Adcetris
ADR Cartridge 1.8
Adrenaline
Cardiovascular
Respiratory
Advantan
Advate
Adynovate
Adjinitor
Aflibercept204 AFT-Pyrazinamide108
Agents Affecting the
Renin-Angiotensin System
Agents for Parkinsonism and Related
Disorders
Agents Used in the Treatment of
Poisonings
Agrylin
Albalon
Albendazole

Albey	266-	-267
Albustix		
Alchemy Oxaliplatin		155
Alchemy Oxybutynin		81
Aldurazyme		28
Alecensa		. 166
Alectinib		166
Alendronate sodium		119
A Loss also a set of a set all some set the		
colecalciferol		119
Alfacalcidol		
Alfamino		
Alfamino Junior		
Alginic acid		
Alglucosidase alfa		26
Alkeran		155
Allerfix		
Allerpro Syneo 1		305
Allerpro Syneo 2		305
Allersoothe		
Allmercap		
Allopurinol		
Almarytm		
Alpha-Adrenoceptor Blockers		46
Alpha-Keri Lotion		
Alphamox 125		
Alphamox 250		
Alprolix		
Alu-Tab		
Aluminium hydroxide		
Alyacen		
Amantadine hydrochloride		123
Ambrisentan		56
Ambrisentan Viatris		
Amgevita		
Amiloride hydrochloride		52
Amiloride hydrochloride with		
furosemide		52
Amilarida hydrochlarida with		
hydrochlorothiazide		52
Aminophylline		273
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